# CHAPTER 3

# OBJECTIVES OF THE GENE TECHNOLOGY BILL

## Introduction

3.1 This chapter examines the adequacy of the measures in the Gene Technology Bill to achieve the Bill's objective of protecting the health and safety of people and the environment, and whether the proposed regulatory arrangements, including the public reporting provisions, will provide sufficient consumer confidence in the regulation of the development and adoption of new gene technologies.

## Objective of the Bill

3.2 The objective of the Gene Technology Bill, as stated in proposed section 3, is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs).

3.3 This objective is to be achieved through a regulatory framework that will be based on an efficient and effective system of assessment and will operate in conjunction with other Commonwealth and State regulatory schemes relevant to GMOs and genetically modified products.[1]

3.4 An important aspect for achieving such an objective is to heed the comment that a critical feature of any regulatory scheme is that it 'remains relevant to the science it oversees, the community it protects, and the industry it regulates'.[2]

## The current regulatory regime

3.5 Before examining the measures contained in the Bill to achieve its objective, the current regulatory system is briefly outlined by way of background to the need for the proposed legislation.

3.6 There are a number of regulatory bodies that currently oversee the use and distribution of genetically modified (GM) products in Australia. These are:

- The Australia New Zealand Food Authority (ANZFA), established by the *Australia New Zealand Food Authority Act 1991* (Cth), develops standards for foods, including genetically modified foods, which are regulated under State and Territory food acts. ANZFA reviews current food standards and processes

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1 Explanatory Memorandum, Gene Technology Bill 2000, p.45.

2 IOGTR, *Fact Sheet 7: A National Regulatory Framework for Genetically Modified Organisms (GMOs)*, p.1.

applications and proposals to amend the Food Standards Code. In addition, it conducts research and surveys in relation to matters that may be included in a food standard and develops food education initiatives in cooperation with the States and Territories. ANZFA is a statutory authority within the portfolio of the Minister for Health and Aged Care.

- The Therapeutic Goods Administration (TGA), pursuant to the *Therapeutic Goods Act 1989* (Cth), is responsible for the regulation of therapeutic goods, including GM therapeutic goods, and human gene therapy, both clinical research and marketing of products for human gene therapy. Regulation of therapeutic goods is achieved through a risk management approach to pre-market evaluation and approval of therapeutic products intended for supply in Australia; licensing of manufacturers; and post-market surveillance. TGA also provides advice to other regulatory authorities on toxicology, pre-market assessment and public health issues relating to agricultural, veterinary and industrial chemicals. TGA is a division of the Department of Health and Aged Care.

- The National Health and Medical Research Council (NHMRC) provides for research funding and advice on all aspects of health and health care delivery in Australia. NHMRC also supervises research involving human gene therapy through its Gene and Related Therapies Research Advisory Panel. NHMRC is a statutory authority established under the *National Health and Medical Research Council Act 1992* within the portfolio of the Minister for Health and Aged Care.

- The National Registration Authority (NRA), established under the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, administers a national regulatory scheme for agricultural and veterinary (agvet) chemicals, including GM agvet chemicals, pursuant to the *Agricultural and Veterinary Chemicals (Code) Act 1994* (Cth). NRA is a statutory authority within the portfolio of the Minister for Agriculture, Fisheries and Forestry.

- The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) regulates industrial chemicals under the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cth) and associated State and Territory legislation. NICNAS provides for mandatory notification and assessment for chemicals that are not covered by other Australian assessment and registration schemes. It aims to ensure that new industrial chemicals entering Australia are assessed for their health and environmental effects before they are used or released into the environment. NICNAS is a statutory scheme administered by the National Occupational Health and Safety Commission, which is a statutory authority within the portfolio of the Minister for Employment, Workplace Relations and Small Business.

- The Australian Quarantine and Inspection Service (AQIS), regulates imports and exports under the *Quarantine Act 1908* (Cth), the *Imported Food Control Act 1992* (Cth) and the *Export Control Act 1982* (Cth). AQIS administers the quarantine, agriculture and food export laws. The Australian Customs Service (ACS), under the *Customs Act 1901* (Cth) provides the primary border control of

imports and exports with the assistance of AQIS. AQIS is a division of the Department of Agriculture, Fisheries and Forestry[3].

3.7 The TGA and the NHMRC also have a research role in addition to their regulatory functions, unlike the other authorities.

*The Genetic Manipulation Advisory Committee (GMAC)*

3.8 GMAC is an independent committee of experts in fields including molecular biology, ecology, plant genetics, agriculture and biosafety[4] engineering. GMAC assesses potential biosafety hazards to the community or the environment and recommends appropriate safety and containment procedures for GMOs to researchers and institutions undertaking work on GMOs. GMAC is concerned with:

> any experiment involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotype produced by genetic manipulation which are either unlikely to occur in nature[5], or likely to pose a hazard to public health or the environment[6].

3.9 As noted in Chapter 1, GMAC recommendations are complied with voluntarily and it has limited capacity for independent, legally enforceable auditing and monitoring of compliance. This current system of overseeing the use of gene technology has no legislative backing.

*The Interim Office of the Gene Technology Regulator (IOGTR)*

3.10 The IOGTR was established as a branch of the Therapeutic Goods Administration within the Commonwealth Department of Health and Aged Care in May 1999, with GMAC acting as expert advisory committee to the IOGTR.

3.11 The function of the IOGTR is:

- to work with representatives of State and Territory Governments, other Commonwealth agencies, existing regulators, and non-government organisations to develop and implement a new national regulatory system for GMOs; and
- pending the establishment of this new system, to provide support and, where necessary, direction to the current voluntary administrative arrangements for GMOs.[7]

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3 Submission No.77, p.18 (IOGTR).

4 Safety with respect to the effects of biological research on humans and the environment.

5 Organisms that are not likely to occur through natural processes, which includes processes other than natural selection (for example, cross-breeding).

6 Submission No.77, p.19 (IOGTR).

7 *IOGTR Quarterly Report*, June 2000.

3.12 Research and development involving GMOs is monitored by GMAC from the initial design concept through each successive stage. Under current arrangements, approval for the commercial release of a GMO must be sought from the Commonwealth Minister for Health and Aged Care. The Minister considers advice from GMAC, the IOGTR, Environment Australia and other experts before making a decision.[8]

3.13 While GMAC has been able to provide reliable scientific advice on the risks posed by gene technology and how to manage those risks, the IOGTR has indicated that the current regulatory arrangements are insufficient for several reasons. Firstly, since there is no legislative backing to the current system, there is no legally enforceable way to audit or monitor the use of the technology or penalise breaches. Secondly, the range of applications for gene technology is changing very rapidly such that GMOs and GM products are now being developed that are not covered by existing regulatory bodies. These include:

- the growing of GM agricultural crops;
- the growing or breeding of GM animals or fish;
- the use of GM micro-organisms designed to decompose toxic substances (bio-remediation);
- stockfeed that may be produced from genetically modified crops, for example cotton; and
- the use of GM viruses and GM vaccines.

Although GMAC has provided advice to the proponents of these GMOs, there has been limited capacity to either monitor or enforce compliance with that advice.

3.14 A third factor is that more GMOs are approaching the commercialisation stage when the producers of the GMOs will be seeking to release the GMO into the environment either for the purposes of field trials or for commercial release.[9]

3.15 Much of the impetus behind the move from a voluntary to a regulatory system of controls has been community perceptions about the risks associated with gene technology and a belief that 'industry cannot be relied upon to be sufficiently rigorous and objective in evaluating risk and implementing appropriate management strategies'.[10]

3.16 A recent case involving breaches of GMAC recommendations in the trialing of genetically modified canola at Mount Gambier highlights the need for a new legislative approach. The investigation into this matter is discussed in Chapter 6.

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8 IOGTR, *Fact Sheet 3: About the Genetic Manipulation Advisory Committee (GMAC)*, p.2.

9 Explanatory Guide, pp.9-10.

10 Submission No.77, p.20 (IOGTR).

**Measures to achieve the Bill's objective**

3.17 The Gene Technology Bill is the major component of a national scheme to protect the public health and safety of people and to protect the environment from risks associated with gene technology. The Bill's objective is to be achieved through the regulation of certain dealings with GMOs based on an efficient and effective system of assessment. Measures in the Bill designed to achieve its objective include:

- the establishment of a statutory officer to be known as the Gene Technology Regulator to administer the legislation and make decisions under the legislation (discussed in Chapter 4);
- prohibiting people from dealing with GMOs except in certain circumstances (see Chapter 4);
- establishing a scheme to assess the risks to human health and the environment associated with various dealings with GMOs (discussed in Chapter 4);
- providing for monitoring and enforcement of the legislation (discussed in Chapter 4);
- the establishment of three key advisory committees (discussed in detail in Chapter 5):
    - the Gene Technology Technical Advisory Committee: to provide scientific and technical advice at the request of the Regulator or the Ministerial Council on gene technology, GMOs and GM products, applications made under the Act, the biosafety aspects of gene technology, and the need for, and content of, policy principles, policy guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products;
    - the Gene Technology Ethics Committee: to provide advice at the request of the Regulator or the Ministerial Council on ethical issues relating to gene technology; the development of codes of practice in relation to ethics in respect of conducting dealings with GMOs; and the development of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons; and
    - the Gene Technology Community Consultative Group: to provide advice at the request of the Regulator or the Ministerial Council, on matters of general concern in relation to GMOs, and on the need for (an content of) policy principles, guidelines, codes of practice and technical and procedural guidelines in relation to GMOs and GM products; and
- providing for a publicly available, centralised database of all dealings in Australia that involve GMOs or GM products (discussed later in this chapter).

3.18 In addition to concerns about the adequacy of measures contained in the Bill to achieve the objective of protecting the health and safety of people and to protect the

environment, many submitters to the inquiry expressed dissatisfaction with the limited scope of the objective and of the Bill in toto.

3.19 The Committee received evidence that was critical of omissions from the objective of the Bill, variously arguing for the inclusion of references to the precautionary principle rather than a precautionary approach, risk reduction rather than risk management, environmental impact and protection of biodiversity, the national interest, human medical research, the ethics of gene technology, animal welfare, and the benefits of gene technology.[11]

3.20 In addition to these concerns relating specifically to the object of the Bill, a number of other issues were raised in relation to achieving the Bill's objective and providing sufficient consumer confidence in the regulation of gene technology. These include the establishment of a moratorium, the role of multinationals, implications for trade competitiveness, trial site locations, commercial-in-confidence information, proposed full cost recovery, adequacy of public reporting procedures, and public confidence.

**The precautionary principle**

3.21 The precautionary principle is based on the concept of taking anticipatory action to prevent possible harm under circumstances where there is a level of scientific uncertainty, although there is much discussion and diversity of opinion as to actually defining the principle.

3.22 The principle, as currently understood, emerged in German law in the 1970s as *Vorsorgeprinzip*[12] used to distinguish between the dangers and the risks caused by human behaviour, with two different approaches required to be taken: to prevent dangers (*Gefahrenvorsorge*) on the one hand, but where there is only a risk of effects occurring, risk prevention must be investigated and if warranted preventative measures applied (*Risikovorsorge*).[13] An enunciation of the principle is that:

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11 See for example Submission No.40, p.1 (Australian Conservation Foundation); Submission No.34, p.3 (Australian Centre for Environmental Law); Submission No.54, p.4 (Organic Federation of Australia Inc); Submission No.86, p.3 (World Wide Fund for Nature and the Humane Society International); Submission No.85, p.8 (ACF GeneEthics Network); Submission No.35, p.6 (GE-Free Tasmania); Submission No.11, p.3 (Canberra Consumers Inc); Submission No.20, p.5 (Ms L McDermott); Submission No.38, p.1 (Mr J Sleeman); Submission No.75, p.1 (Ms N George).

12 The concept is said to have developed from the 1930s German concept of *Vorsorgeprinzip* (foresight planning). 'The Precautionary Principle–"Nothing ventured, nothing gained"?' *Avcare Insights* Vol.1, 2000, p.2 [website: http:www.avcare.org.au/documents/insights.pdf].

13 Wybe Th. Douma, TMC Asser Institute, The Hague, The Netherlands at website: http://www.asser.nl/EEL/virtue/precprin.htm#N_9_.
Other websites that discuss the precautionary principle include:
http://www.icclaw.com/devs/uk/ev/ukev_047.htm;
http://europa.eu.int/comm/off/com/health_consumer/precaution_en.pdf;
http://www.mem.dk/faktuelt/fak15_eng.htm;
http://ehpnet1.niehs.nih.gov/docs/1999/107-12/editorial.html;
http://www.info-france-usa.org/ppseminar/transcript.htm.

> Environmental policy is not fully accomplished by warding off imminent hazards and the elimination of damage which has occurred. Precautionary environmental policy requires furthermore that natural resources are protected and demands on them are made with care.[14]

*The international context*

3.23 Since the early 1980s, a number of multilateral treaties and international declarations and protocols have adopted a form of the precautionary principle. Some examples of the international use of the precautionary principle, which demonstrate a variety of interpretations, include:

> [The participants] accept the principle of safeguarding the marine ecosystem of the North Sea by reducing polluting emissions of substances that are persistent, toxic and liable to bioaccumulate at source, by the use of the best available technology and other appropriate measures. This applies especially when there is reason to assume that certain damage or harmful effects on the living resources of the sea are likely to be caused by such substances, even where there is no scientific evidence to prove a causal link between emissions and effects ("the principle of precautionary action").
> *–1987 Ministerial Declaration of the Second Conference on the Protection of the North Sea.*

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question…in order to avoid or minimize such potential adverse effects.
> *–Cartagena Protocol on Biosafety, 2000.*

> Where action is deemed necessary, measures should be proportionate to the chosen level of protection, non-discriminatory in their application and consistent with similar measures already taken.
> *–EU Communique 2000.*

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation.
> *–1992 Rio Declaration on Environment and Development.*[15]

3.24 With respect to the intentional release of GMOs into the environment, relevant legislation, directives, regulations or guidelines in the European Union,

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14 Review of the Canadian Environment Protection Act (CEPA Review) [website: http://www.ec.gc.ca/cepa/ip18/e18_01.html].

15 Quoted sections are from the CEPA Review or *Avcare Insights*. Other references to the precautionary principle in international conventions, declarations and treaties are listed in Appendix 4.

United Kingdom, United States of America, Japan and South Africa[16] make no explicit reference to the precautionary principle. Appendix 3 provides an international comparison of the regulation of gene technology. However, there is precedent for the precautionary principle to be included in legislation covering GMOs:

- section 7 of the New Zealand Hazardous Substances and New Organisms Act states that all persons exercising functions, powers and duties under this Act shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects; and
- the preamble to the Canadian Environmental Protection Act (CEPA) states that 'whereas the Government of Canada is committed to implementing the precautionary principle that, where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental damage'.[17]

3.25 The differing forms of the precautionary principle also impact on the scope of the principle's application, with some conventions and statements limited to toxic substances control[18], while others include any government policy with the potential to cause environmental degradation.[19]

3.26 One of the areas of dispute is what should trigger the application of the principle, for example 'likely harm' or 'serious or irreversible harm', and who should make such a determination.[20] While there is greater clarity with respect to the implementation of the precautionary approach in the context of ocean dumping, in other contexts its meaning is more elusive.[21]

3.27 Underlying much of the divergence of opinions are the contrasting philosophies of those opposed to the emission of non-natural products into the environment regardless of cost, and those prepared to make environmental trade-offs where there is potential for economic and social benefits. The latter interpretation of the precautionary principle may allow for the use of the best available technology not entailing excessive costs. The 1992 Rio Declaration, for example, includes a reference to 'cost-effective measures'. The former view is summed up by Greenpeace International which emphasized:

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16 Information for Germany is not available, however, it has been argued that Germany's 'overall regulatory approach might be described as a moderate version of the precautionary principle' See CEPA Review.

17 IOGTR, *Overview of International Regulatory Systems for Gene Technology*, August 2000.

18 See for example, the Final Declaration of the Third North Sea Conference, in Appendix 4.

19 See for example, the 1990 Bergen Declaration, in Appendix 4.

20 Compare the 1972 London Convention in Appendix 4 and the 1992 Rio Declaration stated above.

21 CEPA Review.

> the need for an effective precautionary approach, with that important principle intended to safeguard the marine ecosystem by, among other things, eliminating and preventing the release of substances, especially synthetic and persistent substances, where there is reason to believe that damage or harmful effects may be caused, even where there is inadequate or inconclusive scientific evidence to prove a causal link between emissions and effects.[22]

3.28 Regardless of the local variations of the scope and interpretation of the principle, a 'conceptual core' has been described by the Director of the Foundation for International Environmental Law and Development at King's College of London:

> The precautionary principle stipulates that where the environmental risks being run by regulatory inaction are in some way a) uncertain but b) non-negligible, regulatory inaction is unjustified.[23]

3.29 Core elements or directions underlying the precautionary principle include:

- proaction, a willingness to take action in advance of formal scientific proof;
- cost-effectiveness of action, that is, some consideration of proportionality of costs;
- providing ecological margins of error;
- intrinsic value of non-human entities;
- a shift in the onus of proof to those who propose change;
- concern with future generations; and
- paying for ecological debts through strict/absolute liability regimes.[24]

*The Australian context*

3.30 The precautionary principle has been incorporated into Australian legislation and agreements:

> Where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation. In the application of the precautionary principle, public and private decisions should be guided by:
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> i) careful evaluation to avoid, wherever practicable, serious or irreversible damage to the environment; and

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22 CEPA Review.

23 CEPA Review.

24 CEPA Review. Similar points were made by the Wingspread Conference referred to in 'The Precautionary Principle', *Rachel's Environment & Health Weekly*, No. 586, 19 February 1998, Environmental Research Foundation [website: http://www.ratical.org/co-globalize/REHW586.html].

ii) an assessment of the risk-weighted consequences of various options.

Under the principle the "onus of proof" regarding impacts has shifted to those actions that might cause change.
*–Intergovernmental Agreement on the Environment, May 1992.*[25]

The Minister must take account of the precautionary principle in making a decision listed in the table in subsection (3), to the extent he or she can do so consistently with the other provisions of this Act.

The *precautionary principle* is that lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage.
*–Environment Protection and Biodiversity Conservation Act 1999, section 391.*

3.31 The precautionary principle is included as an objective of the New South Wales *Protection of the Environment Administration Act 1991*, which states that 'If there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation'.

*Evidence arguing for and against including the Precautionary Principle in the Bill*

3.32 Many submissions expressed the view that the major deficiency of the Gene Technology Bill was that it does not contain the precautionary principle.[26] Heritage Seed Curators Australia summed up this widely held view by suggesting that the precautionary principle should be inserted in the object of the Bill to express clearly the paramount need for caution in any releases of GMOs. They argued that 'the "precautionary principle" is a simple way of saying that "if we do not know what will happen" it is ill-advised to go ahead and do it!'.[27]

3.33 The Australian Centre for Environmental Law (ACEL) drew attention to Environment Australia's submission to the House of Representatives inquiry into primary producer access to gene technology, which stressed:

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25 Referred to in Submission No.85, p.2 (ACF GeneEthics Network).

26 See for example, Submission No.34, p.4 (Australian Centre for Environmental Law); Submission No.40, p.2 (Australian Conservation Foundation); Submission No.13, p.1 (Mr A Walker-Morison); Submission No.19, pp.1-2 (The Environment Centre of WA); Submission No.22, p.4 (Mr G Whitten); Submission No.85, p.8 (ACF GeneEthics Network); Submission No.35, p.7 (GE-Free Tasmania); Submission No.6, p.3 (Consumers' Association of SA Inc); Submission No.5, p.1 (National Council of Women of Australia); Submission No.106, p.1 (GeneEthics Network); Submission No.16, p.1 (Mr A Ward); Submission No.87, p.1 (Mr & Mrs Underwood); Submission No.66, p.1 (Strider); Submission No.31, p.1 (J Grevillea); Submission No. 30, p.1 (Mr J Langmead); Submission No. 28, p.1 (Ms P Hemsworth); Submission No.15, p.2 (Mr B Holderness-Roddam).

27 Submission No.9, p.3 (Heritage Seed Curators Australia Inc). See also *Committee Hansard*, 24.08.00, p.264 (NGAA) who stated 'Even if no adverse effects have been reported, this does not mean that these will not emerge in the future'.

> The precautionary principle has particular application to GMOs. Not only could direct damage be serious, but ongoing and extensive because of irreversibility. Once released freely to the environment, a living organism, or a novel gene that has transferred to an unintended host, cannot be "recalled". A cautious and conservative approach to risk should be followed where there is insufficient scientific confidence of safety. Successful application of the principle will mean that Australia avoids expensive failures.[28]

3.34 Although characteristic of some opponents of GMOs, support for the application of the precautionary principle in regulating GMOs did not always indicate opposition to the technology, where there was an expressed desire that the technology be a 'benefit to mankind, not…an encumbrance'.[29]

3.35 The Australian Conservation Foundation (ACF) also called for inclusion of the precautionary principle to create certainty, arguing that this can only be achieved by the 'specific mentioning' of the principle in legislation. Mr Kerr of ACF added: 'I would not like to see someone forget that the precautionary principle applies simply because we have not taken five minutes to draft it into the legislation'.[30]

3.36 However it was argued that confusion about how to interpret the principle may itself lead to uncertainty in the operation of the legislation, with the wording in the Biosafety Protocol cited as an example of where the precautionary principle was 'almost grammatical nonsense and extremely difficult to understand'.[31]

3.37 It has also been argued that the terms used in statements of the precautionary principle, such as 'risk', 'uncertainty' and 'serious' have not been defined. Consequently, there is little agreement on the circumstances which warrant the use of the precautionary action or what those actions should be. Opinions have thus polarised: some seeing it as a means for protecting future generations while others a means of stopping research and development.[32]

3.38 The differing view of the precautionary principle was reflected in the Committee's evidence. For some the principle was a general one analogous to the removal of land mines.[33] Others however, understood it to mean that a technology could not be progressed unless there was certainty about its future risks:

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28 Cited in Submission No.34, p.4 (Australian Centre for Environmental Law).

29 *Committee Hansard*, 22.08.00, p.78 (Mrs L Huebner). See also, *Committee Hansard*, 23.08.00, p.162 (Mr A Macintosh).

30 *Committee Hansard*, 24.08.00, p.315 (ACF).

31 *Committee Hansard*, 24.08.00, p.246 (Australian Biotechnology Association).

32 *Avcare Insights*, p.2. See also, for example, R Horton, 'Genetically modified food: consternantion, confusion, and crack-up', *MJA* 2000, 172:148-149 [Article published on the Internet by *The Medical Journal of Australia* website: http://www.mja.com.au].

33 *Committee Hansard*, 22.08.00, p.65 (Heritage Seed Curators Australia Inc).

> The precautionary principle, as I understand it, would mean that you do not do anything unless you are absolutely 100 per cent certain that there is no risk. I do not think we can say that there is any technology we can progress to that extent. If we take the literal meaning of the precautionary principle, I would not support it, but I would support a precautionary approach.[34]

3.39 However the precautionary principle as written in Australian environmental policy and the *Environment Protection and Biodiversity Conservation Act 1999* (Cth) (EPBC Act) applies a lesser test than 'absolute 100 per cent certainty that there is no risk'. The obligation on regulators is to consider identified risks carefully:

> where there are threats of serious or irreversible environmental damage, lack of scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation.

3.40 If the Regulator is aware of threats to the environment, then the obligation is to take action even if there is a lack of scientific certainty about the extent of the threat. There has to be sufficient evidence that the threats are credible and would result in serious or irreversible damage.

3.41 In the case of GMOs this would suggest that the Regulator should postpone approval for release of GMOs where it is believed there was a threat of serious or irreversible environmental damage. Equally the Regulator might apply the principle to decide to approve an application subject to a rigorous set of conditions to forestall or minimise any threats of damage even if there was not scientific certainty that those measures would be absolutely necessary.

3.42 Florigene Limited and Nugrain Pty Ltd argued, that while they 'are not opposed to incorporating sound science-based precaution into regulatory procedures':

> We are firmly of the view that indiscriminate use of the precautionary principle will stifle technological advancement and investment and as a consequence, reduce the capacity of agriculture to respond to future demands for its products, both in Australia and internationally.[35]

3.43 Professor Peter Gresshoff argued:

> While it is natural for our species to fear the "unknown", and while I accept that "zero risk" technology is unattainable, I believe it is essential that we as

34 *Committee Hansard*, 23.08.00, p.188 (Serve-Ag). See also Submission No.9, p.3 (Heritage Seed Curators Australia Inc). Cf. Submission No.93, p.1 (Dr K Clinch-Jones) who argued that commercial interests should come second to the protection of humans and the environment.

35 Submission No.42, p.4 (Florigene Limited and Nugrain Pty Ltd). See also, for example Submission No.105, p.1 (Australian Cotton Cooperative Research Centre).

> a society of thinking and rational individuals venture on the side of reason rather than superstition and hear-say.[36]

3.44 The possibility that a development should not proceed where the potential adverse effects were not fully understood was included in the World Charter for Nature (1982):

> Activities which are likely to pose a significant risk to nature shall be preceded by an exhaustive examination; their proponents shall demonstrate that expected benefits outweigh potential damage to nature, and where potential adverse effect are not fully understood, the activities should not proceed.[37]

3.45 Many of those arguing in favour of the precautionary principle used historical examples of 'science gone wrong' to further their argument, citing for example the adverse effects of thalidomide, DDT or the release of certain animals such as the cane toad for biological control.[38]

3.46 However, this view was countered by other cases where opposition to beneficial scientific advances was poorly substantiated, for example halting vaccination and opposition to fluoridation.[39]

3.47 The IOGTR informed the Committee that the Commonwealth, States and Territories had examined in detail the issue of including a reference to the precautionary principle in the Gene Technology Bill 2000. All jurisdictions noted that there was continuing debate both internationally and within Australia on the scope and application of the precautionary principle. The jurisdictions considered that some sectors of the community perceived the precautionary principle as being about non-action or not taking a decision, arguing instead that:

> In reality, the Precautionary Principle allows governments to take action and decide upon measures in circumstances where there is a serious or irreversible threat to the environment but the available scientific evidence may be inconclusive.[40]

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36 Submission No.100, pp.1-2 (Professor P Gresshoff). See also, *Committee Hansard*, 24.08.00, p.283 (AWB Ltd).

37 World Charter for Nature, UN GA Resolution 37/7 (1982), 11(b) [See website http://sedac.ciesin.org/pidb/texts/world.charter.for.nature.1982.html].

38 *Committee Hansard*, 24.8.00, p.264 (National Genetic Awareness Alliance). Other cases include the introduction or use of organochlorins, asbestos, and DES – diethylstilboestrol - which had been used in medicine and agriculture for 30 and 25 years respectively. *Avcare Insights*, p.1; See also Submission No.113, p.1 (Ms M Sculthorp); *Committee Hansard*, 23.8.00, p.142 (OFA); *Committee Hansard*, 23.8.00, p.165 (Mr G Whitten); C*ommittee Hansard*, 24.8.00, p.309 (ACF GeneEthics Network).

39 *Committee Hansard*, 24.08.00, p.246 (Australian Biotechnology Association). See also *Committee Hansard*, 23.08.00, p.186 (Serve-Ag).

40 Submission No.77, p.74 (IOGTR).

3.48 In recognition that an explicit reference to the precautionary principle may create potential uncertainty about its interpretation, all jurisdictions agreed that the risk assessment and risk management approach contained in the Bill embodied an appropriate precautionary approach without being directly stated. To ensure that a precautionary approach is applied by the Gene Technology Regulator, the legislation:

- empowers the gene technology regulator to obtain scientific evidence from a range of sources, including his/her own independently commissioned research;
- requires the regulator to identify risks to people or the environment posed by each dealing;
- requires the regulator to determine a risk management plan for each dealing;
- requires the regulator to reject the application if the risks cannot be managed (i.e. if the dealing presents a serious or irreversible threat);
- requires the regulator to establish a monitoring program;
- requires the regulator to take or order remedial action if required; and
- ensures that the regulator is publicly accountable for decisions.[41]

3.49 The Committee is cognisant of the potential risks associated with the release of GMOs into the environment and that this is the primary concern of most people advocating the adoption of the precautionary principle in relation to the regulation of GMOs. To avoid uncertainty, the Committee considers that any reference to the precautionary principle should be expressed in terms consistent with those used in Australian precedents including the EPBC Act.

3.50 Despite variations in defining the principle, the need for the precautionary principle to be included in the object of the Bill and to be applied by the Regulator when making decisions on licence applications, received considerable support in submissions and during the Committee's hearings.[42]

3.51 The adoption of the principle is not unprecedented, with the precautionary principle entrenched in both the EPBC Act and the Cartagena Biosafety Protocol, to which Australia is not yet a signatory.[43] It was emphasised that the push for the inclusion of the principle in the Gene Technology Bill did not stem from groundless

41 Submission No.77, p.74 (IOGTR).

42 See for example, *Committee Hansard*, 23.08.00, p.180 (GE-Free Tasmania); *Committee Hansard*, 24.08.00, p.305 (ACF); Submission No.54, p.6 (Organic Federation of Australia Inc).

43 *Committee Hansard*, 24.08.00, p.305 (Australian Conservation Foundation); *Committee Hansard*, 25.08.00, pp.357, 371 (ACEL).

fear but from a real need to exercise caution in relation to a technology for which the long-term effects are yet to be fully studied or understood.[44]

3.52 It was argued that gene technology should not merely be viewed as a scientific field but also an industrial technology and that the inclusion of the precautionary principle in the Bill should serve as a benchmark for the regulation of other new industrial technologies.[45]

3.53 The Committee supports the precautionary approach to the introduction of gene technologies at a time when much scientific research is being done around the world to quantify the extent, if any, of the risks of serious or irreversible environmental damage, or risks to human health.

3.54 The Committee notes the concern raised about the way in which the handling of BSE infected beef has influenced many people's cautious attitudes towards GMOs, particularly genetically modified foods. While it is acknowledged that this incident did not involve GMOs, it is considered to be an example of where a precautionary approach may have prevented a major public health problem.

3.55 The Committee further notes the recent decision to prevent Australians who lived in the UK during the height of the BSE scare from donating blood. This decision was made despite the extremely small risk that CJD could be passed through blood donations and represents a precautionary approach to the possible risk that has been welcomed by experts and the general public alike.

3.56 The requirement in section 391 of the EPBC Act for the Minister to consider the precautionary principle in making a range of decisions was cited by many in evidence as a valuable precedent. The Committee is concerned that legislation covering the protection of the environment provides through the inclusion of the precautionary principle a more stringent precautionary approach than that which is being proposed for the protection of human health and safety in the Gene Technology Bill. Nevertheless, the Committee welcomes the measures included in the Bill to ensure that a precautionary approach is applied, but considers that without the precautionary principle explicitly stated in the legislation, other measures such as extending standing for third-party appeal to the Administrative Appeals Tribunal (see Chapter 5) must be included to ensure that measures to protect the health and safety of people are stringent.

## A precautionary approach

3.57 The overwhelming majority of submitters to the inquiry recognised the need to adopt a cautious approach in relation to the regulation of GMOs and differed only in the degree of caution required. The difference centred on the adoption of either a

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44 *Committee Hansard*, 22.08.00, p.62 (Heritage Seed Curators Inc); *Committee Hansard*, 25.08.00, p.371 (ACEL). See also *Committee Hansard*, 23.08.00, p.222 (Tasmanian Government).

45 *Committee Hansard*, 24.08.00, p.309 (ACF GeneEthics Network).

precautionary approach or the explicit statement of the precautionary principle in the legislation, notably in the object and licensing provisions of the Bill.

3.58 This view was highlighted during the First Australian Consensus Conference on Gene Technology in the Food Chain which observed:

> The potential hazards are largely unknown in the long-term and as such demand due caution during the research, development and initial use of GMOs.[46]

3.59 The Committee notes that the Cartagena Protocol's objective reaffirms the 'precautionary **approach'** enshrined in Principle 15 of the Rio Declaration on Environment and Development rather than the precautionary principle itself. The Committee also notes that CSIRO was unable to identify any legislation of similar scope and intent as the Gene Technology Bill 2000 where the precautionary principle was intended but not explicitly stated.[47]

3.60 The June 2000 report of the House of Representatives Standing Committee on Primary Industries and Regional Services *Work in Progress: Proceed with Caution*, recommended the continued use of gene technology, but only with 'stringent regulation, constant and cautious monitoring, and public reporting'.[48]

3.61 While the precautionary principle was not favoured in all evidence presented to the Committee, a precautionary **approach** was considered sufficient to ensure that risks associated with GMOs were identified and properly managed without stopping potentially beneficial research and development of GMOs, and without requiring the expectation of absolute certainty in science, an unattainable aim.[49]

> What we are saying is that a precautionary approach should be applied to risk management. Once an organism has been approved, then it has to be managed under farming conditions, and we have a lot of examples where best management practice is the tool to actually manage that risk. So we certainly believe that a precautionary approach should be applied in that area of risk management.[50]

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46 Lay Panel Report, First Australian Consensus Conference on Gene Technology in the Food Chain [website: http://www.austmus.gov.au/consensus]

47 CSIRO, Additional Information dated 25.August 2000, p.3.

48 *Work in Progress: Proceed with Caution*, Report by the House of Representatives Standing Committee on Primary Industries and Regional Services, June 2000, p.29.

49 *Committee Hansard*, 25.08.00, p.426 (CSIRO); Submission No.90, p.1 (Du Pont Technical Centre). See also Submission No.94, p.2 (Monsanto Australia Ltd); Submission No.98, p.2 (Novartis Australia Pty Ltd); Submission No.104, p.1 (Dow AgroSciences).

50 *Committee Hansard*, 25.08.00, p.381 (Avcare).

3.62 The adoption of the precautionary approach was supported by Dr Lonsdale from CSIRO, who also commented on the attitude of CSIRO scientists to the precautionary principle:

> I think you would find within our organisation there are a range of views on the precautionary principle: there are those for whom it is the very essence of science, and there are those for whom it is the antithesis of science. Ultimately, the precautionary approach is probably the one I would subscribe to, because I am aware of the very great problem facing agriculture and biodiversity in this country and overseas, and I do not think we can tie our hands behind our backs. So I would argue that moving forward cautiously, making haste slowly-the precautionary approach-is the approach to take, rather than the principle which seems to me to argue for doing nothing until absolute certainty is achieved, which in science is impossible.[51]

3.63 The Committee notes that a precautionary approach rather than precautionary principle is contained in the South Australian *Environment Protection Act 1993* which includes in its objectives (sub-section 10(1)(b)) a commitment:

> to apply a precautionary approach to the assessment of risk of environmental harm and ensure that all aspects of environmental quality affected by pollution and waste (including ecosystem sustainability and valued environmental attributes) are considered in decisions relating to the environment.

3.64 While there is clearly consensus on the need to ensure a cautious approach to the development and adoption of gene technologies, there is also acknowledgment of the need to ensure the continuation of research and development on the basis of current scientific understanding of potential risks:

> [The] Regulator's deliberations must be based on sound, consistent and reproducible scientific and technical data generated according to world best practice standards.[52]

3.65 The adequacy of science to identify all of the potential risks and detect hazardous cause and effect consequences associated with biotechnology has been questioned. Reasons for this concern include:

- limitations in scientific knowledge;
- problems of statistical power (producing false negatives);
- low-level adverse effects;

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51 *Committee Hansard*, 25.08.00, p.426 (CSIRO).

52 Submission No.42, p.4 (Florigene Limited and Nugrain Pty Ltd). See also, *Committee Hansard*, 23.08.00, p.184 (Serve-Ag Pty Ltd) for support for a 'responsible and regulated' cautious approach to use of gene technology.

- difficulties in addressing cumulative effects; and
- financial and resource limitations which make it too expensive to test all product and environmental combinations.[53]

3.66 The Committee notes the view expressed by the IOGTR about the ability of the regulatory procedures to protect the community:

> No regulatory system can guarantee absolute safety or zero risk. However, Australia already has an extremely good record on the regulation of food, chemicals and pharmaceuticals that are genetically modified.[54]

3.67 A number of organisations considered that the measures provided for in the Bill would enable the Regulator to meet the objectives of the legislation.[55] For example, the Grains Research and Development Corporation stated:

> The establishment of an independent regulator with the power to enforce decisions on GMO use should ensure the protection of health and the environment, and, importantly, the community's confidence that the protection is being provided.[56]

3.68 The National Farmers' Federation (NFF) considered that in addition to the measures outlined above, the requirement for the Regulator to report to Parliament in the event of serious breaches of the legislation and the strict liability attached to breaches of licence conditions should ensure high consumer confidence.[57]

3.69 While the Institute of Public Affairs considered that measures in the Bill were more than adequate to meet its objectives, claiming that 'there is considerable overkill since the technology poses no threat to humans and is likely to improve environmental outcomes',[58] others expressed scepticism that the objectives could be achieved given that the 'scientific discovery of DNA is less than 50 years old and the gene pool has developed and matured or diversified over billions of years'.[59]

3.70 Ms Lisa McDermott concurred, stating:

> A genetically engineered organism is uniquely different to every other organism on the planet. We cannot possibly know the consequences of

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53 *Avcare Insights*, p.5.

54 IOGTR, Gene Technology Bill 2000, Questions and Answers, p.14.

55 See for example, Submission No.89, p.3 (Tasmanian Government); Submission No.105, p.1 (Australian Cotton Co-operative Research Centre); Submission No.8, p.2 (Serve-Ag Pty Ltd); Submission No.71, p.11 (Australian Food and Grocery Council); Submission No.63, p.5 (AWB Ltd); Submission No.102, p.2 (CSIRO).

56 Submission No.41, p.1 (Grains Research and Development Corporation).

57 Submission No.88, pp.1-2 (National Farmers' Federation).

58 Submission No.78, p.1 (Institute of Public Affairs Ltd).

59 Submission No.101, p.1 (Ms F Murrell). See also, Submission No.64, p.1 (Mr P Hockey).

> restructuring living organisms which in billions of years of evolution have never crossed species boundaries. Those who realise and acknowledge this will feel a little more cautious and be more inclined to act responsibly about gene technology.[60]

3.71 The paradox of gene technology is that there is considerable uncertainty about the extent of risks at this time. Being too cautious may stifle research that might clarify the extent of such risks and unnecessarily restrict work to determine the extent of benefits that gene technology may bring. However, unless care is taken, it is possible that if problems are identified in the future the applications might be too widespread to be able to counter the harmful effects.

3.72 The Committee considers that the precautionary approach would be underpinned in the Bill if the precautionary principle appeared as one of the objects in the same form as it appears in the EPBC Act. The Committee does not support the precautionary principle being made a specific test in the licensing provisions.

3.73 The Committee considers that there is a balance between the risks to the community versus the rights of a company,[61] and strongly considers that, in keeping with a precautionary approach, the onus of proving that GMOs are not harmful should rest with the proponents of the technology.

**Risk management versus risk prevention**

3.74 Some submissions expressed concern at the use of 'risk management' as an object of the Bill rather than risk prevention or reduction.[62] It was argued that the onus should be on the applicant to show that the work being undertaken was not harmful or unethical,[63] and that where the outcomes may be irreversible, 'the concern of the GTR then must be to prevent and eliminate such risks'.[64]

3.75 The Committee understands concerns raised in evidence about the emphasis on risk management rather than risk prevention. The Committee considers that risk identification, assessment and management should be based on the most up-to-date and independent scientific advice available at the time of the application for a licence. The adequacy of the risk assessment processes is discussed in Chapter 4.

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60 Submission No.20, p.1 (Ms L McDermott).

61 See for example, *Committee Hansard*, 24.08.00, p.268 (NGAA) who stated that 'industry concerns should not override health and safety concerns'.

62 Submission No.34, p.3 (Australian Centre for Environmental Law); Submission No.86, p.3 (World Wide Fund for Nature and The Humane Society International); Submission No.54, p.4 (Organic Federation of Australia Inc); Submission No.79, p.1 (Mr K Healy).

63 Submission No.75, p.1 (Ms N George).

64 Submission No.73, p.1 (Ms J Ablitt).

## Environmental impact

3.76 The Committee considers that while the protection of the environment is important, it should not detract from the paramount objective of protecting the health and safety of people.[65] The Committee supports the placement of the OGTR in the Health and Aged Care portfolio.

3.77 The Committee notes the concern raised by ACF that 'there is no requirement under the GT Bill that an environmental impact assessment (EIA) of a proposed GMO dealing take place'.[66]

3.78 The objective of the Bill was also considered inadequate because of its failure to refer to ecological sustainability. The ACF Gene Ethics Network recommended:

> The Objects of the GT Bill 2000 should also be amended to include the principle of ecological sustainability, to ensure GEOs do not contribute to the long term destabilisation and decline of our food and fibre production systems, the natural environment and biological diversity.

3.79 The Committee notes that the procedures for assessing the environmental impact of GMOs were considered inadequate to protect the environment as required by the objective of the Bill. Chapter 4 includes a discussion of the adequacy of risk assessment processes under the Bill.

*Biodiversity*

3.80 The Environment Protection and Biodiversity Conservation Act includes in its objectives (section 3) the protection of Australia's biodiversity. A number of submissions recommended that one of the objects of the Gene Technology Bill should be to protect, conserve and maintain biological diversity against threats posed by GMOs.[67]

3.81 Mr Ian Dowden and Ms Kathleen Canning argued:

> Scientists are unsure of how GMOs will react in the open environment. In particular they are uncertain as to how GMOs will interact with other species and their capacity to mutate. As in the case of exotic species (eg the rabbit, cane toad and the prickly pear), the release of GMOs into the open environment could have unforeseen and catastrophic consequences.[68]

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65 The Committee notes, for example, the recommendation that the objective of the Act should be amended to add, 'but with an overall priority being given to public health and occupational health'. See Submission No.111, p.4 (Dr I Furzier).

66 Submission No.40, p.2 (Australian Conservation Foundation). See also *Committee Hansard*, 24.08.00, p.308 (ACF).

67 Submission No.51, p.3 (Friends of the Earth (Fitzroy)); Submission No.73, p.2 (Ms J Ablitt); Submission No.79, p.1 (Mr K Healy).

68 Submission No.49, pp1-2 (Mr I Dowden & Ms K Canning).

3.82 The Committee notes the recommendation of the World Wide Fund for Nature and the Humane Society International that the EPBC Act should be amended to include GMO releases as a matter of national environmental significance, in order to ensure full environmental assessment and to give the Environment Minister power to veto GMO releases where necessary for environmental protection.[69]

3.83 Mr Anton from the ACEL observed:

> Environmental impact assessment is only "triggered" where there is likely to be a significant impact on the environment under the EPBC Act, as determined by the minister. If it is taking place in a contained, closed area-in research, if you will-and it is determined under the EPBC regime that it is not likely to have a significant environmental impact, then there is no need and no occasion to prepare an environmental impact assessment.[70]

3.84 The Committee notes the advice that if the Regulator were concerned that the release of a GMO may impact on species diversity, the Regulator would not approve the application to release the GMO.[71] Avcare Limited argued:

> It is not necessary for biological diversity matters to be included as they can be considered as part of the environmental assessment conducted by the Environment Minister. In the situation where the release is to be made onto areas of national significance could trigger the Environment Protection and Biodiversity Conservation Act (Part 3).[72]

3.85 The Committee notes that in the current Bill, the Regulator must seek advice from the Environment Minister in preparing a risk assessment and risk management plan for applications that may involve the intentional release of a GMO into the environment. This differs from the 1999 draft Bill, where the Environment Minister is not specifically mentioned. The Committee is not satisfied that this change provides sufficient strengthening of the overall risk assessment processes with respect to the impact of GMOs on the environment.

3.86 The Committee considers that, given the scope of the Bill which includes the protection of the environment, any measures needed to ensure this objective should be contained within the Gene Technology Bill itself rather than referring to another Act. The relationship between the Bill and the EPBC Act with respect to environmental risk assessments is discussed in Chapter 4.

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69 Submission No.86, p.2 (World Wide Fund for Nature and the Humane Society International). See also, Submission No.28, p.1 (Ms P Hemsworth).

70 *Committee Hansard*, 25.08.00, p.367 (ACEL).

71 IOGTR, Gene Technology Bill 2000, Questions & Answers, p.13.

72 Submission No.32, p.5 (Avcare Limited).

**Recommendation**

**The Committee RECOMMENDS that the risk assessment provisions of the Bill should be amended to give greater weight to the consideration of the impact of the release of GMOs into the environment, especially given Australia's unique flora and fauna and the importance of maintaining Australia's biodiversity.**

**The national interest**

3.87 The consultation draft of the Gene Technology Bill circulated in 1999 included in its object, in addition to the primary objective of protecting human health and the environment, a reference to the national interest:

> It is also an object of this Act that dealings with GMOs be regulated in a way that is consistent with Australia's national interests.[73]

3.88 The present Bill's object does not refer to the national interest, an omission criticised in evidence to the Committee.[74] It was considered important that the regulatory framework was seen to be operating in the national interest rather than a private or secular interest.[75]

3.89 Mr Gary Burgess from the SA Farmers Federation stated:

> …the national interest could mean that we wish to encourage a biotechnology industry in Australia, and it may be in our national interest not to allow certain products to come in without an Australian partner and things like that…currently, if you were to take national interest out, providing everything is hunky-dory through the rest of the act, there is then no provision to say, "No, we're not going to accept that piece of technology".[76]

3.90 The Consumers' Association of SA proposed:

> We would like to see an objective here that spells out the protection of Australia's diverse farming systems as being in the national interest. It was the term "national interest" in the first draft not being defined, that left open "matters of trade" as being seen as in the national interest to the detriment of our diverse farming systems and possibly other matters such as public or community interest.[77]

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73 Consultation Draft Gene Technology Bill 2000, sub-clause 3(2).

74 *Committee Hansard*, 22.08.00, p.48 and Submission No.81, p.1 (South Australian Farmers Federation); *Committee Hansard*, 22.08.00, p.127 (Aventis Crop Science Pty Ltd).

75 *Committee Hansard*, 22.08.00, p.50 (South Australian Farmers Federation).

76 *Committee Hansard*, 22.08.00, p.53 (SA Farmers Federation).

77 Submission No.6, p.2 (Consumers' Association of SA Inc).

3.91 As with the precautionary principle, there is lack of clarity as to how the expression 'national interest' should be interpreted.[78] The Committee notes that 'national interest' was not defined in the draft Bill but included matters that may have been specified in policy guidelines or codes of practice developed in accordance with the Gene Technology Intergovernmental Agreement. The Bill provides that the Ministerial Council may issue policy guidelines in relation to matters relevant to the functions of the Regulator.[79] The role of the Ministerial Council is examined in detail in Chapter 5.

**Human medical research**

3.92 Concern was expressed about the failure to include clinical research which involves gene technology within the scope of the Bill. Ms Kathy Liddell stated:

> It is claimed that these matters are dealt with by the NHMRC in much the same way that certain activities are handled by the regulatory authorities mentioned above. However, the regulatory power of the NHMRC is relatively weak. It is primarily based on Guidelines that are part of funding agreements. It does not have strong powers to monitor compliance and are only voluntarily binding on some organisations. If the Bill is not extended to cover clinical research that uses gene technology, this particularly risky application of gene technology will be regulated the least stringently of all GM dealings.[80]

3.93 Canberra Consumers stated that 'there should be some comment, perhaps along the lines that genetic modification of humans is excluded but will be picked up in other legislation'.[81]

3.94 The IOGTR advised that the original draft had defined a GMO to exclude a human being, but that this had led to concerns that trials involving the use of GMOs in humans would not be covered by the Bill. This has been clarified in the current Bill which excludes people who have undergone somatic[82] cell therapy, who may then, under the previous definition, have been required to be licensed. Under the current legislation the GTR will regulate all organisms modified by gene technology including human cell lines and tissue samples. While the TGA and the NHMRC will have the primary responsibility for overseeing somatic cell gene therapy, the GTR will

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78 See for example, *Committee Hansard*, 22.08.00, p.53 (South Australian Farmers Federation) *Committee Hansard*, 22.08.00, p.109 (National Council of Women of Australia Ltd).

79 Gene Technology Bill 2000, clause 23.

80 Submission No.45, p.3 (Ms K Liddell). See also *Committee Hansard*, 24.08.00, p.312 (ACF GeneEthics Network) who expressed concern about 'human genetic engineering' and the need for it to be regulated by the Gene Technology Bill.

81 Submission No.11, p.4 (Canberra Consumers Inc).

82 Body cells as opposed to sperm and ova.

also be involved to ensure that there are no environmental risks posed by GMOs to be used as part of the human trials.[83]

3.95 While other regulatory authorities will continue to have carriage of the regulation of GMOs relevant to their area of responsibility, the Regulator will still play an advisory role.[84] The Gene Technology (Consequential Amendments) Bill 2000 requires existing regulators to:

- seek advice from the Gene Technology Regulator in relation to any application for approval of a GM product;
- take such advice into account in decision making under relevant legislation; and
- notify the Regulator of all decisions made in relation to GM products to enable those decisions to be entered on a central, publicly available database of all GMOs and GM products held by the Regulator.[85]

3.96 The confusion over the scope of the Bill in relation to human medical research highlights a major criticism expressed in evidence to the Committee – that of the interaction between other regulatory authorities and the proposed Gene Technology Regulator backed by calls for a 'one-stop shop' approach to be adopted. This is discussed in detail in Chapter 4. The appropriateness of the advisory role of the Regulator is also examined.

3.97 The Committee notes that in a late submission, concerns were raised about the possibility that the Gene Technology Bill would permit human cloning.[86] The Committee also notes that there is disquiet about suggestions that human cloning be covered by the Bill, and concurs with the view expressed by the Queensland Government that 'human cloning raises complex and sensitive issues which are probably best dealt with in separate legislation'.[87] The Committee notes that the House of Representatives Standing Committee on Legal and Constitutional Affairs is currently conducting an inquiry into the scientific, ethical and regulatory aspects of human cloning.

**Recommendation**

**In view of the confusion caused by the lack of clarity on the status of medical research, and particularly human medical research, under the legislation the Committee RECOMMENDS that the Bill be amended, where appropriate, to explicitly state how such research will be dealt with by the OGTR.**

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83 IOGTR, Additional Information dated 25 August 2000, Attachment D.

84 IOGTR, Additional Information dated 25 August 2000, p.9.

85 Explanatory Memorandum, Gene Technology (Consequential Amendments) Bill 2000, p.1.

86 See Submission No.116 (Mr N Tonti-Filippini). Submission 65 (Mr A McKinley) also stated that the Government should legislate against human cloning.

87 Submission No.84, p.2 (Queensland Government).

## Ethical considerations

3.98 According to some submitters the social, religious and ethical implications of gene technology, including transgenic organisms,[88] were issues to be considered in the regulation of GMOs.[89] It was argued that these issues should be outlined in the object rather than in guidelines or policy directives of the Gene Ethics Committee.

3.99 The Committee was reminded that these issues are held very deeply by many people:

> While the threat to human health and the environment is of vital importance, the government must be mindful of the fact that many people believe that GE involves an immoral meddling with "nature" or "God's creation".[90]

3.100 The ethical issues associated with gene technology were accorded a high priority by the First Australian Consensus Conference held in Canberra in March 1999. The Conference, which brought together a group of experts and lay people, concluded:

> There are many moral and ethical issues raised by gene technology such as:
>
> – Should life become a commercial property through patenting?
>
> – Should we create transgenic organisms, particularly those containing human and animal DNA?
>
> – Who advocates for nature?
>
> – How do we ensure that our decision-making processes respect the diverse cultural, moral and religious beliefs within our multicultural society?
>
> It would be presumptuous of us to answer these issues or to assume that we have identified all of them, however we believe that ethical considerations must assume a prominent role in decision making about gene technology.[91]

3.101 The Lay Panel's Report recommended that an ethicist be involved in the formulation of major decisions regarding GMO policies.

3.102 The IOGTR advised the Committee that:

> no statutory ethics committee is involved in providing policy guidance in New Zealand, Japan, South Africa, Canada or the United States. Likewise,

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88 Organisms that have had a foreign gene inserted into them.

89 See for example Submission No.38 (Mr J Sleeman) and Submission No.75 (Ms N George). *Committee Hansard*, 24.08.00, p.322 (ACF). See also Submission No.35, p.15 (GE-Free Tasmania).

90 Submission No.25, p.16 (Mr Andrew Macintosh).

91 Lay Panel Report, First Australian Consensus Conference on Gene Technology in the Food Chain.

> in the United Kingdom there are several advisory committees composed of a range of individuals, but there is no specific expert committee established to advise on ethics. Similarly, domestically, AQIS, TGA, NICNAS, ANZFA and the NRA all operate without the influence of an expert ethics committee.[92]

3.103 Under the Gene Technology Bill, the Regulator 'must not accept an application for a licence to deal with a GMO if it is inconsistent with a prohibitive ethical principle'.[93]

3.104 The proposed Gene Technology Ethics Committee is to be established to deal with the very issues raised by some submitters to the inquiry. The Committee notes that the Bill provides that the Ministerial Council may issue policy guidelines in relation to ethical issues relating to dealings with GMOs. The appropriateness of this provision and the relationship between the Ministerial Council and the Gene Technology Ethics Committee is discussed in Chapter 5.

**Animal welfare**

3.105 While the Bill's object addresses the health and safety of people and the environment, Friends of the Earth (Fitzroy) raised the issue of animal welfare, recommending that the object include a reference to the health and safety of animals.[94]

3.106 Avcare Limited, on the other hand, argued:

> It is not necessary for animal health to be included as animals can be considered as part of the environment into which the GMO is being released. Furthermore, proponents of GMOs still have to comply with other relevant legislation such as State animal welfare legislation.[95]

3.107 IOGTR advised that all States and Territories have legislation in place to protect the welfare of animals and prevent cruelty to animals, including in the context of animal research. In all jurisdictions, other than Western Australia, the animal protection legislation refers to the NHMRC's *Australian code of practice for the care and use of animals for scientific purposes* (the NHMRC code).[96]

3.108 The NHMRC code covers 'all aspects of the care and use of, or interaction with, animals for scientific purposes in medicine, biology, agriculture, veterinary and other animal sciences, industry and teaching'. This includes their use in research,

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92 Submission No.77, p.120 (IOGTR).

93 IOGTR, Gene Technology Bill 2000, Questions and Answers, p.7.

94 Submission No.51, p. 3 (Friends of the Earth (Fitzroy)). Re biological diversity, see also Submission No.73, p.2 (Ms J Ablitt).

95 Submission No.32, p.5 (Avcare Limited).

96 IOGTR, Additional Information dated 3 October 2000. [For a copy of the Code, see NHMRC's website http://www.health.gov.au/nhmrc/publicat/ea-home.htm].

teaching, field trials, product testing, diagnosis, the production of biological products and environmental studies.[97]

3.109 Additionally, guidelines for the humane conduct of scientific and teaching activities, and for the acquisition of animals and their care, including their environmental needs, are specified in the NHMRC code. All live non-human vertebrates are covered by the NHMRC code, which requires that 'eggs, fetuses and embryos must be treated in a humane manner where development of an integrated nervous system is evident'.[98]

3.110 The IOGTR advised that the Bill, when enacted, will not exclude the operation of any other State laws, and is in addition to, not a substitution for, the requirements of other Commonwealth laws. Any person undertaking research involving genetic modification and animals must comply with both the Gene Technology Bill and any other relevant State and Commonwealth legislation.[99]

3.111 The Committee notes that where issues arise in relation to gene technology and animals that are not adequately addressed under existing State legislation and the NHMRC code, the Ministerial Council may, on the advice of the Gene Technology Ethics Committee, issue policy principles or policy guidelines regarding ethical issues including animal welfare issues.

3.112 IOGTR further stated that prior to accepting an application, the Regulator will ensure that the application not only accords with any ethical guidelines issued by the Ministerial Council but also that the application is in accordance with relevant State/Territory laws for the protection of animals.[100] Any application that is not in accordance with such requirements will be rejected by the Regulator.[101] The Regulator may also prescribe certain codes of practice relating to ethics and animal welfare as a condition of a licence.[102]

3.113 The Committee notes that while there is state legislation that covers animal welfare, it is concerned that the Ministerial Council would be left to address any shortfalls in regulations covering animal welfare.

**Recommendation**

**The Committee RECOMMENDS that relevant State and Territory animal welfare legislation and the NHMRC code of practice for the care and use of animals for scientific purposes, be examined to determine whether more**

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97 Synopsis of NHMRC code (see website).

98 Synopsis of NHMRC code (see website).

99 IOGTR , Additional Information dated 3 October 2000.

100 IOGTR , Additional Information dated 3 October 2000.

101 IOGTR, Gene Technology Bill 2000, Questions & Answers, p.15.

102 IOGTR , Additional Information dated 3 October 2000.

**stringent provisions need to be applied with respect to animals and genetic modification.**

### Benefits of gene technology

3.114 Concerns were expressed that the facilitating benefits of gene technology were not included in the object of the Bill. It was argued that this was contrary to a Commonwealth Government Ministers' announcement about the planned legislation, that the purpose of the gene technology regulatory system should be to 'realise the benefits of gene technology for the Australian community, industry and the environment, while ensuring human safety and environment protection'.[103]

3.115 The Committee acknowledges that there are potential benefits to the community and the environment from gene technology, but considers that an important purpose of the Bill is to ensure public confidence in the regulation of this technology. The Committee notes that organisations involved in the research, development and commercialisation of GMOs currently play a role in the dissemination of information and education of the community about the benefits of gene technology. However, the Committee considers that it would be more appropriate for an independent organisation to provide a balanced approach to the provision of information on the benefits **and risks** of gene technology.

3.116 In addition to the concerns just discussed relating specifically to the object of the Bill, a number of other issues were raised in relation to achieving the Bill's objective and providing sufficient consumer confidence in the regulation of gene technology. These are discussed in the remainder of this chapter.

### Alternative regulatory models

3.117 The Australian Centre for Environmental Law provided the Committee with an alternative model Act for the comprehensive regulation of all activities and dealings involving gene technology.[104] A number of witnesses supported this model Act arguing that it provided a more effective regulatory framework to achieve the Government's stated object of the Gene Technology Bill.[105]

3.118 Alternative regulatory models, including the 'one-stop shop' are examined in Chapter 4.

### Placement of a moratorium

3.119 A number of groups supported the placement of a moratorium on gene technology including a freeze on:

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103 Submission No. 41, pp.1-2 (Grains Research and Development Corporation).

104 Submission No.34 (Australian Centre for Environmental Law).

105 *Committee Hansard*, 24.08.00, p.305 (ACF). See also, for example Submission No.25, p.3 (Mr A Macintosh); Submission No.22, p.2 (Mr G Whitten); Submission No.35, p.6 (GE-Free Tasmania).

- the further introduction of genetically engineered crops or foodstuffs into Australia;[106]
- the release of GMOs into the environment;[107]
- GMOs until proven to be benign to humans and other life forms;[108]
- the general release of GMOs, including medical GMOs;[109]
- gene technology to allow for 'some sort of scientific consensus and the market implications of this technology to emerge';[110] and
- uncontained field trials or field crops.[111]

3.120 A moratorium was also considered essential to allow time to inquire into the need to revamp relevant legislation in the light of the uncertainty and vagueness surrounding the assessment of the risks associated with gene technology.

> I believe that if we revamp all our acts that underlie this gene technology bill we can overcome those things because we are going to put into effect greater securities and greater sureties in practical issues and these should be worked out. This is what I am saying. We need a five year moratorium in which to do that and do it appropriately, thoroughly, efficiently properly and ethically.[112]

3.121 The Committee notes that the Tasmanian Government has instituted a 12 month moratorium on the open research or trialing of GM crops during which time the Tasmanian Parliament will examine the implications of gene technology for Tasmania. Tasmania's position is discussed in Chapter 6 in the context of its support for the inclusion of an opt-out clause in the Bill.

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106 Submission No.54, p.3 (Organic Federation of Australia Inc); Submission No.51 (Friends of the Earth (Fitzroy)), p.1. See also *Committee Hansard*, 24.08.00, p.267 (NGAA) who recommended a ban on 'foods made by genetically modified organisms in artificial formulas and in baby foods' and pp.271 (NGAA) who also recommended a moratorium on patenting of GMOs.

107 See for example, Submission No.4 (Mrs S Stafford); Submission No.5 (National Council of Women of Australia); Submission No.69 (Friends of the Earth (Perth WA Group)); *Committee Hansard*, 22.08.00, pp.64, 91 (Heritage Seed Curators Australia Inc); *Committee Hansard*, 23.08.00, p.161 (GE-Free Tasmania); *Committee Hansard*, 23.08.00, p.138 (Organic Federation of Australia Inc).

108 Submission No.24 (Bio-Dynamics Tasmania), p.2.

109 *Committee Hansard*, 22.08.00, p.65 (Heritage Seed Curators Inc). See also *Committee Hansard*, 23.08.00, p.161 (GE-Free Tasmania).

110 *Committee Hansard*, 23.08.00, p.138 (Organic Federation of Australia Inc).

111 Submission No.21, p.1 (Mrs U Mueller).

112 *Committee Hansard*, 22.08.00, p.88 (Ms L Huebner). Ms Huebner also stated re the type of legislation that required amendment: 'There is the plant breeders patenting act and allied acts, and also the privacy acts…they relate to commercial confidentiality. (p.78).' See also, *Committee Hansard*, 24.08.00, p.266 (NGAA) who argued that a moratorium would allow a 'social and economic assessment, assessing of patenting, strict legal liability, can the law keep up with technology, prevention of genetic pollution, and greater public involvement and awareness of gene technology'.

## The role of multinationals

3.122 GE-Free Tasmania stated that 'to date the interests of biotechnology companies have dictated the nature of the GE debate…However, this has served to stimulate considerable public concern about the safety of GE and the intentions of those involved in its development and commercialisation'.[113] Submissions pointed to public disquiet over the role of multinational companies in promoting gene technology onto an unwilling public. NT Bio Dynamic Network argued that many people 'have no confidence in science altering our food for the benefit of Multi National Companies. There are no known benefits for GM food to be forced onto consumers'.[114]

3.123 The commitment of multinational corporations to the safety of GMOs and its impact on the agricultural sector was questioned by Ms Vicki Brooke:

> The technology has the potential to undermine our whole agricultural sector as it has been built up over generations since the early nineteenth century, since it is promoted by agrichemical companies anxious to sell their product, clearly acknowledged by Monsanto when its Director of Corporate Communications said "Monsanto should not have to vouchsafe the safety of our biotech food. Our interest is in selling as much as possible. Assuring its safety is the FDA's job".[115]

3.124 Concern was also expressed about the potential misuse of gene technology by multinationals:

> Poverty and oppression contribute to famine and hunger. Gene technology could perhaps in the future promote famine and hunger if it promotes the need for cash to pay the corporations and if the corporations become oppressive.[116]

3.125 Dr Tribe commented on the dangers associated with the potential dominance of gene technology by multinational companies:

> The whole notion of having high regulatory hurdles and the whole rigour of regulation, arguably out of proportion to risks, encourages only the very strong to survive that rigorous path. So that has to be realised…If a lot more encouragement were given to more ventures, more institutes and smaller activities, and they were able to see a path forward to the market, that would be good.[117]

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113 Submission No.35, p.14 (GE-Free Tasmania). See also, for example, Submission No.114, pp.1-2 (Ms B Rosser).

114 Submission No.3, p.1 (NT Bio Dynamic Network). See also Submission No.48, p.1 (Ms S Kyriacou).

115 Submission No.27, p.8 (Ms V Brooke).

116 Submission No.68, p.3 (Ms H Swainston).

117 *Committee Hansard*, 24.08.00, p.254 (ABA).

3.126 However, according to the IOGTR concerns about the dominance of multinationals in gene technology have been addressed:

> The legislation has…been drafted so as not to impose unfair burdens on small industry nor entrench overly restrictive practices between companies and for example, contract farmers.
>
> If individual companies do…engage in unfair or restrictive trade practices, this will be a matter for consideration by the Australian Competition and Consumer Commission – the independent statutory watchdog administering the *Trade Practices Act 1974* and the *Prices Surveillance Act 1983*.[118]

**Implications for trade competitiveness**

3.127 The Committee received conflicting views on the impact of the proposed regulatory regime on Australian trade opportunities.[119] These included, for example, reports about loss of market share for the sugar industry, which may be recovered with the assistance of gene technology:

> CSIRO researchers…are trying to produce sugarcane which yields the lower colour sugar that attracts premium prices internationally.
>
> …the key to the research was to regulate an enzyme in the cane which causes browning in fruit and vegetables.
>
> …lowering the colour even 20 or 30 per cent…will be of benefit to the industry which has lost market share in recent years to competitors like Brazil which have produced quite a low colour sugar.[120]

3.128 The NSW Farmers' Association warned 'we do not want to see this issue being used as a weapon against industries faced with much more rigorous requirements than its competitors'.[121]

3.129 The Committee recognises the difficulties faced by the Government in ensuring the safety of people and the environment, and, at the same time, ensuring that Australia's trade and economic opportunities are not unnecessarily damaged through over regulation of this technology. However, the Committee considers that in keeping with the object of the Bill, the Government must link the health and welfare of the Australian people and protection of the environment with trade considerations in a field of science for which the long-term risks and hazards are yet to be sufficiently understood.

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118 IOGTR, Gene Technology Bill 2000, Questions and Answers, p.13.

119 *Committee Hansard*, 24.08.00, p.293 (AWB Ltd).

120 *Bid to turn sugar a whiter shade of pale*, AAP, 4 July 2000.

121 Submission No.76, p.2 (NSW Farmers' Association).

## Trial site locations

3.130 Many groups and individuals criticised the secrecy associated with field trials of GMO crops and argued that information relating to trials and their site locations should be publicly available to improve confidence in the system.[122]

3.131 The District Council of Grant in South Australia expressed concern at the lack of information on trial sites made available to local councils. The Council submitted that '**No** notification is supplied to the Council or the public, regarding the location of the trial sites, duration, size, and conditions pertaining to the trialing of genetically modified crops (for example Canola)'.[123]

3.132 There was also concern that the location of dealings involving the general release of GMOs could be declared confidential commercial information:

> The argument that this is necessary to protect property and personal safety does not outweigh the great harm the gene technology industry is doing to its public image. It is worth noting that in Europe, where there is widespread opposition to gene technology, the location of GMO crops is not concealed as it is here.[124]

3.133 While Tasmanian Alkaloids was prepared to publicise future trial sites[125], the NFF drew on overseas experience to argue against this proposition, and considered that the destruction of or damage to trial sites should be made an offence under the Bill. Other companies currently involved in gene technology trials supported the NFF's position.[126]

3.134 Novartis explained that while they agreed that there was a 'genuine need for openness' with respect to the location of trial sites to support confidence in the process, their experience in the UK, where in a spirit of openness the company had supported the practice of revealing the precise location of sites, was 'that such disclosure led to trial site vandalism to such a degree that some of the current farmscale biodiversity evaluations are now in jeopardy'.[127]

3.135 Others claimed that the incidence of vandalism of GMO crops should not be used to justify the non-disclosure of trial site locations, arguing that 'security alarm

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122 See for example, Submission No.99, p.3 (Ms K Harris) and Submission No.51, p.9 (Friends of the Earth (Fitzroy)).

123 Submission No.60, p.1 (District Council of Grant).

124 Submission No.35, p.9 (GE-Free Tasmania).

125 *Committee Hansard*, 23.08.00, p.216 (Tasmanian Alkaloids Pty Ltd).

126 Submission No.88, p.2 (National Farmers' Federation). See also Submission No.32, p.7 (Avcare); Submission No.42, p.6 (Nugrain and Florigene); Submission No.76, p.4 (NSW Farmers' Association).

127 Submission No.98, p.2 (Novartis Australia Pty Ltd). See also Submission No.90, p.1 (Du Pont Technical Centre); Submission No.94 (Monsanto Australia Ltd); Submission No.104 (Dow AgroSciences); Submission No.32, p.7 (Avcare Limited). See also *Committee Hansard*, 23.08.00, p.187 (Serve-Ag).

systems may have to be put in place to protect GE crops but farmers as well as the public have a right to know this information'.[128]

3.136 The Committee condemns any acts of vandalism against GMO field trials and is concerned that such acts may themselves facilitate the dispersal of GM pollen resulting in the types of contamination that must be prevented.[129]

3.137 Avcare, an umbrella organisation of biotechnology companies, proposed an alternative approach to providing information on trial site locations:

> [that] Avcare members…make the locations of trials available to an independent third party who could be contacted by a concerned grower. The grower would then be told whether a trial was nearby and, if so, directed to the proponent of the trial for information.[130]

3.138 The Organic Federation of Australia was critical that this proposal required organic farmers to advise GMAC of the location of their crops around Australia:

> ...it is going to cost us money to do that. We have farmers who declare that they grow oilseed but, because we do not know whether they grow it in that particular year, we have to write to 1,000 or 2,000 farmers who might grow it. We have a 20,000 tonne organic canola crop, and we ask, 'Are you growing it or not?' So there is a cost involved. We have said that, if the government is willing to repay us for that cost, we will consider it.
>
> …if you do that for organic farmers, then you have to do that for beekeepers, and why shouldn't you do that for any conventional canola farmer out there around Australia?[131]

3.139 The Committee considers that Avcare's proposal may undermine confidence in the GTR and confuse the public in relation to where information on trials and other issues concerning the regulation of gene technology should be sought. The Committee supports the views of the Organic Federation of Australia and considers that it is more appropriate for GM growers to make details of trial site locations available to those who may be affected.

**Commercial-in-confidence information**

3.140 Environs Kimberley felt that the commercial-in-confidence provisions of the Bill would undermine the object of the Bill to protect human health and safety.[132]

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128 Submission No.20, p.2 (Ms L McDermott).

129 See *Committee Hansard*, 23.08.00, p.217 (Tasmanian Alkaloids Pty Ltd) who states that 'damaging things is not the right way to conduct a debate'.

130 Submission No.32, p.7 (Avcare Limited). See also Submission No.98, p.3 (Novartis Australia Pty Ltd); Submission No.90, p.1 (Du Pont Technical Centre).

131 *Committee Hansard*, 23.08.00, p. 146 (Organic Federation of Australia Inc).

3.141 The importance of transparency was also stressed by Professor Adrian Gibbs:

> If the public is to have faith in the regulation of gene technology, very little of the data upon which the Regulator has made a decision should be permitted to be hidden from scrutiny on the grounds that it is commercially sensitive information, and even if it is, then the type of each item of information must be declared, even though the specific details may be hidden. Thus, for example, an interested member of the public must be able to determine for an approved GMO whether a particular type of safety feature has been examined and considered by the Regulator, even though the details of the outcome of the test may be hidden. Otherwise, if there is no public record of the type of information being withheld, then the public record, in toto, is valueless.[133]

3.142 Others, while recognising that the public has a right to information about the development of GMOs, were concerned at the ramifications of revealing too much in a competitive market-place:

> sooner or later you will reach a point where all we will see in Australia is last year's technology or 10-year-old technology. It will be absolutely generic and fully disclosed. We will never see state-of-the-art, highly competitive technology–especially if we are looking for technology that will give products a competitive edge in the international marketplace.[134]

3.143 Mr Kim Healy considered that the Bill should include a 'precise definition of commercial confidentiality' and added:

> The GTR should always have the power to override the claim for confidentiality in the public interest, as when human lives or environmental damage are threatened.[135]

3.144 The IOGTR advised that the current Bill requires the GTR to refuse to declare information to be confidential commercial information if the public interest in disclosure outweighs the prejudice the disclosure would cause.[136]

**Recommendation**

**The Committee would consider it undesirable if commercial in confidence information compromised the objectives of the Bill or the transparency of the regulatory regime, and RECOMMENDS that where an application for an intentional release of a GMO into the environment includes the size and location**

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132 Submission No.82, pp.7-8 (Environs Kimberley). See also, Submission No.21, p.1 (Ms U Mueller); Submission No.95, p.1 (Mr D Adams MP).

133 Submission No.70, pp.2-3 (Professor A Gibbs).

134 *Committee Hansard*, 24.08.00, p.340 (Nugrain Pty Ltd).

135 Submission No.79, p.1 (Mr K Healy).

136 IOGTR , Additional Information dated 25 August 2000, Attachment D.

**of this proposed release, the information should be made available publicly providing that the penalties for any intentional damage to that release are an effective deterrent against eco-terrorism.**

3.145 The issue of the information to be taken into account by the Regulator when making a decision on whether a licence should be granted is discussed in Chapter 4.

### Cost recovery

3.146 The proposed full cost recovery to fund the OGTR was identified as one of the measures that could potentially undermine the objective of the Bill.[137] The Committee notes that this proposal has recently been assessed by KPMG. The issue of cost recovery, the KPMG report and implications for parliamentary accountability, are discussed in Chapter 4.

### Adequacy of public reporting provisions

3.147 The Bill includes a number of public reporting provisions that must be observed by the Regulator. These include requirements to:

- report to Parliament annually, and on other occasions as may be required, about matters relating to the function of the Regulator;[138]
- establish a GMO Register;[139] and
- provide a Record of GMO and GM Product Dealings.[140]

3.148 The IOGTR advised that the Record of GMOs and GM product dealings would list all dealings with GMOs and GM products approved for use in Australia, regardless of whether they were produced domestically or imported. Approval must be sought from the Australian Quarantine and Inspection Service (AQIS) for the importation of a live or viable GMO, to ensure there are no pest and disease or quarantine risks. Approval must also be sought from the Regulator who is required to check the biosafety of the GMO. If either AQIS or the GTR considers that the risks of import are too high, on either quarantine or biosafety grounds, the GMO cannot be imported. In the event that the importation of the GMO is approved, details of the approval will be entered on the Record.[141]

3.149 GE-Free Tasmania argued that the Record should also include the location of all dealings. They further suggested that:

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137 See for example, Submission No.58, p.1 (Australian Biotechnology Association); Submission No.71, p.11 (Australian Food and Grocery Council).

138 Gene Technology Bill 2000, ss.136-7.

139 Gene Technology Bill 2000, s.76.

140 Gene Technology Bill 2000, s.138.

141 IOGTR , Additional Information dated 5 October 2000.

- the wording of sub-clause 138(3) should explicitly provide that 'the information regarding licences must include all variations, cancellations and suspensions made to licences';
- information about exempt dealings should also appear on the Record;
- the scope of the Record should include all accredited organisations and certified facilities; and
- the term 'GM product dealings' be clarified for the purpose of clause 138.[142]

3.150 The Australian Conservation Foundation was also critical of information that would not be available on the Record and recommended the inclusion of the following information:

> (a) the application for the licence, and if the application is denied, the reasons why the Regulator decided to refuse the licence;
>
> (b) all information submitted in support of an application for a licence authorising dealings with GMOs issued under Part 5 of the GT Bill;
>
> (c) the name of the licence holder;
>
> (d) the persons covered by the licence;
>
> (e) the activities or dealings authorised by the licence;
>
> (f) licence conditions;
>
> (g) the date on which the licence was issued, and the reasons why the Regulator decided to issue the licence;
>
> (h) all information collected in the course of monitoring and/or auditing of the licence; and
>
> (i) any variations, suspensions or cancellations of the licence.[143]

3.151 The IOGTR advised that, in the 1999 draft Bill, the Record of GMOs and GM product dealings would only have included information about the licences issued by the GTR. However, after the consultation process, this had been expanded to include information about:

- notifiable low risk dealings; and
- all approvals granted by any other regulatory agency in relation to GM products.

3.152 The IOGTR also advised the Committee that the Record of GMOs will not include a list of failed applications for approvals to deal with GMOs and GM products. It stated that the purpose of the Record is to provide the Australian public with easy and immediate access to a comprehensive list of those dealings with GMOs and GM products that have been approved in Australia, and which may directly affect

142 Submission No.35, pp.10-11 (GE-Free Tasmania).

143 Submission No.40, pp.6-7 (ACF).

them, including approvals of GM products made by other regulators, which must be notified to the Gene Technology Regulator.[144] The Record will take the form of a comprehensive publicly available database on the GTR's website.

3.153 The IOGTR indicated that while the Record will not contain a list of failed applications, the public will have access to the failed applications through the public consultation process. For example, in the case of applications involving intentional release of a GMO into the environment, the GTR will consult the public on the application and the draft decision. As such the public will have access to, and be able to comment on, the full reasons for non-approval as set out in the GTR's draft decision (risk assessment and risk management plan).[145]

3.154 Mr Greg Whitten was critical of the Register of GMOs, claiming that 'there is no public consultation process involved - the Regulator can make a decision on whether a GMO is listed on the Register without consulting anyone'. He also expressed concern that such a Register would allow 'easy access of these GMOs into GE free zones'.[146]

3.155 There was also a suggestion that a register of accidental releases of GMOs into the environment should be established.[147]

3.156 Mr Anton from the Australian Centre for Environmental Law noted that the Register required under the EPBC Act was more comprehensive than the one proposed under the Gene Technology Bill, and argued that the Register of GMOs should include 'as a minimum…details involving the application, where the release is going to take place, and those things for public protection'.[148]

3.157 However, Mr Burgess, representing the SA Farmers Federation, argued against the Register containing details of a licence, stating:

> …while supporting the need for transparency in the licensing system, there is also a need to protect those seeking and who have been granted a licence to utilise gene technology.[149]

3.158 The 1999 draft of the Gene Technology Bill did not include a provision for a Register of GMOs. The Register was included in the current Bill following concerns raised during public consultations. It had been argued that in cases where a GMO, for example a cut-flower, was considered to be safe and dealt with (as defined by the Bill)

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144 IOGTR , Additional Information dated 3 October 2000.

145 IOGTR , Additional Information dated 3 October 2000.

146 Submission No.22, p.14 (Mr G Whitten). See also Submission No.35, p.8 (GE-Free Tasmania).

147 Submission No.96, p.1 (Ms F Murdoch).

148 *Committee Hansard*, 25.08.00, p.363 (ACEL).

149 *Committee Hansard*, 22.08.00, p.48 (SA Farmers Federation).

by millions of people, that a single company should not be required to hold a licence for that product.

3.159 The IOGTR advised that the GTR would be able to enter GMOs on the Register after a period of licensing and demonstration of the absence of risk, which would allow anyone to deal with the GMO without the need for a single licence holder.[150]

3.160 Both the Record and the Register will be accessible via the GTR's website and the public will also be able to request that extracts from the Record or the Register be mailed to them.[151]

3.161 There was also some misunderstanding as to the frequency of reports to be made and to whom, whether the Minister or the Parliament directly.[152] Under clause 136 of the Bill, the Regulator must prepare for the responsible Commonwealth Minister a report on the operations of the Regulator as soon as practicable after the end of the financial year. The Minister must table the report to each House within 15 days of receipt of the report. The Regulator must also provide a copy of the report to each State.

3.162 Under clause 137 of the Bill, the Regulator may cause a report about matters relating to the Regulators' functions to be tabled in either House of the Parliament, and must give any such report to the Minister for Health and Aged Care and the States.

3.163 The Committee understands this clause to mean that where a report on a matter was requested by the Parliament, the Regulator must provide such a report directly to the Parliament. The Committee considers that the clause would benefit from clarification to ensure that any such report is provided to **both** Houses of Parliament. The Committee also considers that the Regulator must report on any breaches of licence conditions or guidelines which have caused serious environmental damage or harm to human health or safety as soon as practicable after the breach.

3.164 The Committee considers that annual reporting by the Gene Technology Regulator is insufficient. The Committee notes that in May 2000, the IOGTR advised the Minister for Health and Aged Care that it would, in future, report on a quarterly basis in line with the it's aim of providing interested people with more timely and comprehensive information about current oversight of GMOs.[153]

3.165 The Committee believes that the Bill should be amended to add a requirement for quarterly reports on compliance with the legislation which includes information on

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150 IOGTR, Additional Information dated 25 August 2000, Attachment D.

151 IOGTR, Additional Information dated 25 August 2000, p.3.

152 See for example, *Committee Hansard*, 25.08.00, p.392 (Avcare) and pp.405-6 (AFGC).

153 *IOGTR Quarterly Report*, June 2000.

who received licences and for what purposes, and details of any investigations into breaches of licence conditions (see Chapter 4).

3.166 The Committee supports the extended use of the OGTR's website to provide timely information, in addition to the publication of quarterly and annual reports.

**Public confidence**

3.167 Many of the concerns about the Bill's object are tied to the ability of the Regulator to deliver a system that will restore and maintain public confidence in the proposed regulatory arrangements. Two of the most important factors bearing on the public acceptance of the proposed regulatory regime are the transparency of the assessment process and the independence of the Regulator.[154]

3.168 The Australian Food and Grocery Council stated:

> …for the maximum benefit and confidence of consumers we require a regulatory framework which is transparent, fully accountable, and, very importantly, independent of commercial, political and sectoral influence. Consumer confidence in the application of gene technology and the safety of its products is fundamental to investment in, and the subsequent commercialisation of, the technology.[155]

These issues are discussed in detail Chapters 4 and 5 of this report.

3.169 The Committee received evidence from those who want greater regulation in order to meet the objective of the Bill and ensure consumer confidence in the regulation of GMOs, and those who feel that the problem lies with insufficient public education.[156] Others considered that the Bill had been drafted with public safety in mind and provided adequate safeguards designed to enhance consumer confidence.[157]

3.170 CSIRO stated that, in addition to ensuring 'rigor and scientific underpinning' of the Regulator's decision-making:

> Ensuring consumer confidence will require significant attention to implementing the broader strategic issues as encompassed in the recently launched National Biotechnology Strategy and, in particular, urgent and decisive action on enhancing public awareness by unbiased information being provided by community, industry and government organisations. Without such information, the public acceptance and adoption of gene

154 See for example, Submission No.109, p.1 (Dr A Campbell).

155 *Committee Hansard*, 25.08.00, p.397 (Australian Food and Grocery Council).

156 See for example, Submission No.36, p.3 (Valley Seeds Pty Ltd). See also, *Committee Hansard*, 23.08.00, p.236 (Tasmanian Government).

157 See for example, Submission No. 32, pp.6-7 (Avcare Limited); Submission No.88, p.7 (National Farmers' Federation); Submission No.89, pp.3-4 (Tasmanian Government); Submission No.91, p.1 (Western Australian Government).

> technologies and their products into Australia could be delayed or even prevented in the immediate future.[158]

3.171 Valley Seeds also considered public education important despite other measures included in the Bill aimed at ensuring consumer confidence in the regulation of GMOs:

> All these measures, however will account for little if the public is not educated about the process. A high level of education is more likely to prevent public concern than any level of reporting on its own.[159]

3.172 This view was supported by Mr Buz Green of Serve-Ag Pty Ltd:

> I am finding that there is a profound lack of knowledge and understanding of the technology and the science behind it in the community. I think that if more effort were made to educate the public, then that would, I am sure, improve their confidence. Over history fear is one of the first things with any new technology, but as knowledge is increased, fear tends to be reduced.[160]

3.173 The assumption that more information will automatically ensure greater public acceptance of gene technology was criticised:

> …attempts to cast the debate as a battle of beneficent and knowledgeable cleverness versus ignorant and superstitious anxiety should be resisted. Regulators need to acknowledge that the public has well founded grounds to be ambivalent about genetic technology. No amount of instruction in molecular biology, education on the economic benefits of research and innovation, and the need to be internationally competitive can allay legitimate human concerns.[161]

3.174 This view was supported by Mr Hankin from Heritage Seed Curators Australia who argued that a lack of technical understanding of gene technology should not be used to disparage the opinions of people opposed to GMOs.[162]

3.175 The Committee notes the Commonwealth Industry Minister's strategy for responding to the concerns held by some in the community about gene technology:

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158 Submission No.102, p.3 (CSIRO). See also *Committee Hansard*, 24.08.00, p.242 (Dr Tribe) who argued consumer confidence in GMOs was low because 'there is a huge amount of misinformation being spread by people who are against GMOs for reasons that are not really scientifically well explained and who wish to portray, in order to achieve their political objectives, this technology as being morally dubious'.

159 Submission No.36, p.3 (Valley Seeds Pty Ltd).

160 *Committee Hansard*, 23.08.00, pp.190-1 (Serve-Ag).

161 Submission No.95, p.44 (Mr D Adams, MP).

162 *Committee Hansard*, 22.08.00, p.63 (Heritage Seed Curators Australia Inc). See also *Committee Hansard*, 25.08.00, pp.429-430 (Professor A Gibbs).

> …we have an obligation to demonstrate the opportunities for improvements to our health, in benefits to the environment and in enhancing the competitiveness of our industries as a result of biotechnology.[163]

3.176 The CSIRO noted that the pace of technological change also affected public confidence:

> What we see…is that some citizens in countries around the world feel very uncomfortable with technological change. It happens that biotechnology is one raft of technological change which is currently moving past us. One hundred years ago we felt equally uncomfortable in societies about the advent of the internal combustion engine and the loss of horses and carriages; we do not bemoan that now.[164]

3.177 The Committee considers that there is more substance to the concerns of opponents for them to be dismissed as the views of a 'noisy minority'.[165] While acknowledging the complexity of concepts and techniques used in gene technology and understanding the need to provide explanations in a way that lay-people can understand them, the Committee considers that it is time to move from the provision of overly simplistic descriptions to more detailed and objective accounts of the processes associated with the development of GMOs, particularly those likely to enter the food chain.

3.178 The Committee notes the observations of GE-Free Tasmania:

> To date, the interests of biotechnology companies have dictated the nature of the GE debate and the actions of the Federal government. However, this has served to stimulate considerable public concern about the safety of GE and the intentions of those involved in its development and commercialisation. The GT Bill must facilitate public involvement in the application of gene technology so as to ensure that it can be applied in an effective and prosperous manner. The current provisions of the GT Bill will only add to the public distrust and scepticism and potentially stifle the adoption of beneficial uses of gene technology.[166]

3.179 Concern over the involvement of biotechnology companies in the dissemination of public information was emphasized Ms Herminie Swainston, who stated:

> The electorate needs to have enough balanced information about gene technology to make informed decisions. This may reduce the extent to which people are manipulated and indoctrinated by vested interests who have lots of money to spend on persuading us that their GMOs are OK, safe

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163 Quoted in *Government launches national biotech strategy*, AAP, 3 July 2000.

164 *Committee Hansard*, 25.08.00, p.421 (CSIRO).

165 See Submission No.61, p.5 (Aventis CropScience Pty Ltd).

166 Submission No.35, p.14 (GE-Free Tasmania).

> and fully tested, even if they aren't. We need protection by responsible government that has not done deals with the corporations.[167]

3.180 In Europe, information on gene technology is disseminated by consumer and environmental organisations, schools/universities, industry and government. In most cases, the most widely trusted information sources are those provided by consumer and environmental groups. The issue is not one of robustness or accuracy of information, but trust. The role of the media in influencing public perceptions is also significant. Information provided by a range of media is 'often misleading, inaccurate, and incomplete'.[168] The role of the media in the dissemination of information on gene technology was also criticised in evidence to the Committee:

> I would urge the committee to give weight to the evidence which has proper scientific basis and reject the myth and misinformation that is being perpetuated in this debate…If you go around the world…you see the same messages coming out. The media obviously perpetuates a lot of it, but where it emanates from I am not too sure.[169]

3.181 Another approach, first developed and used in Denmark in the mid 1980s, is the consensus conference which brings together relevant experts and lay people. Other European countries have adopted the model, modified to fit the local political culture.[170]

3.182 Australia held its first consensus conference in March 1999 on gene technology in the food chain. Over nine days, a Lay Panel comprising people with no prior knowledge of the topic and representing a range of attitudes and values, set questions for a panel of experts who came from science, industry, environment, religion and public health. A number of concerns were highlighted as a result of the conference, including:

- consumers are mistrustful and cynical;
- people feel excluded from decision-making;
- ethical and moral considerations are major issues;
- while recognising the perceived benefits people see technology as serving the interest of a privileged few, that is, multinational companies;

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167 Submission No.68, p.2 (Ms H Swainston).

168 Mendiata, NL and Lints FA. 'Novel and transgenic food crops: overview of scientific versus public perception', *Transgenic Research*, 1998, 7:379-386.

169 *Committee Hansard*, 23.08.00, p.185 (Serve-Ag).

170 Mendiata, NL and Lints FA (1998). For information on public consultation on biotechnology in OECD countries, see [http://www.oecd.org/dsti/sti/s_t/biotech/act/consultations.htm].

- that there should be more caution and less haste in applying new technologies.[171]

3.183 The Committee notes that the Lay Panel recommended that better processes to allow public access to information, which includes varying perspectives, should be established at many levels, including:

- the establishment of a gene technology information office;
- government sponsored advertising campaigns;
- toll-free phone lines and Website for consumer information;
- public notices on GM issues;
- information fact sheets; and
- focused education information and CD Roms.

3.184 The Lay Panel also recommended that increased consumer representation on existing and future decision making bodies 'is absolutely necessary'.[172]

3.185 The Gene Technology Bill provides for extensive community participation in GMO assessment processes. The role and composition of the proposed Gene Technology Community Consultative Group is discussed in Chapter 5.

3.186 In referring to the impact on public perception of genetic modification with respect to fresh fruit and vegetables, Australian United Fresh Fruit & Vegetable Association and Fresh Produce Watch considered that:

> Consumer reassurance about safety and environmental effects of GM fresh produce is the role of Government which has to ensure adequate and thorough assessment, control, monitoring and the provision of unbiased information.[173]

3.187 In 1999, the Australian Government announced the establishment of Biotechnology Australia (BA) with the aim of consolidating information on, and increasing public awareness about, biotechnology. The Committee notes that the goal of Biotechnology Australia is to ensure that Australia captures the benefits arising from the medical, agricultural and environmental application of biotechnology, while protecting the safety of people and the environment.[174]

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171 *Gene technology and food*, National Science & Industry Forum Report, Australian Academy of Science, April 1999, p.10.

172 Lay Panel Report, First Australian Consensus Conference on Gene Technology in the Food Chain.

173 Submission No.56, p.1 (Australian United Fresh Fruit & Vegetable Association Ltd and Fresh Produce Watch).

174 See Biotechnology Australia's website [http://www.isr.gov.au/ba/].

3.188 Biotechnology Australia developed the National Biotechnology Strategy which was launched in July 2000, which encapsulates the Commonwealth's vision for biotechnology:

> Consistent with safeguarding human health and ensuring environment protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.

3.189 In acknowledging the purpose for which Biotechnology Australia was established, the Committee accepts that BA is perceived to have a pro-gene technology bias, notwithstanding its fact sheet *The Arguments For 'n' Against Genetic Manipulation*[175] and other general information provided for the public. A brochure produced by BA for distribution to Australian supermarkets entitled *Genetically Modified Foods – Information and answers to your questions* was described by the Australian Consumers' Association as a 'sales brochure for GM foods'.[176]

3.190 The Committee notes the conclusions drawn by the recent House of Representatives report, *Work in Progress: Proceed with Caution*, which recommended that Biotechnology Australia be established as a statutory authority to ensure that it is, and is seen to be, independent to overcome the distrust the consumers have of government agencies.

3.191 The need for a source of objective information on the benefits and risks of gene technology that presents both sides of the debate is becoming increasingly urgent.

3.192 The Committee notes that a 1998 postal survey of attitudes to genetic engineering and food conducted by the Consumer Science Program at CSIRO Health Sciences and Nutrition, Adelaide, found that most respondents would trust information provided to them by CSIRO scientists. Among the least trusted were government agencies, food manufacturers and the companies using the new technologies, with the news media rated last.[177]

3.193 The Committee acknowledges the valuable contribution that CSIRO is making to gene technology research and awareness. CSIRO currently conducts three main gene technology public awareness activities:

*Gene Technology Information Program*

3.194 This program was established in 1998 to provide balanced and factual information on the benefits and risks of gene technology, which brought together a

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175 See the BA website under Education, Factsheets. See for concerns about BA's pro-GM bias, see for example, *Committee Hansard*, 24.08.00, p.280 (NGAA).

176 Submission No.95, p.44 (Mr D Adams, MP).

177 National Science & Industry Forum Report, April 1999, p.15.

number of activities previously run by individual Divisions of CSIRO as well as initiating new activities including:

- participating in the Biotechnology Australia public awareness program (since 1999) [BA website: http://www.isr.gov.au/ba/];
- providing background scientific information to the media;
- producing radio interviews with scientists in the *Sci Files* CSIRO radio series [CSIRO education website: http://www.csiro.au/];
- sponsoring and helping organise Australia's First Consensus Conference on Gene Technology in the Food Chain, Canberra, March 1999 [website: http://www.austmus.gov.au/consensus/];
- organising National Science Briefings for members of parliaments in Canberra, Adelaide and Melbourne on the subject of gene technology;
- producing six short video clips about gene technology research as part of CSIRO's Australia Advances television series (funded by BA);
- organising a special gene technology feature in the science magazine *The Helix* [magazine website: http://www.csiro.au/helix/dhthehelix.html];
- launching a website providing scientific information about gene technology in Australia [http://genetech.csiro.au/] (funded by BA); and
- piloting a public telephone enquiry service for Biotechnology Australia (funded by BA).

*CSIRO Plant Industry communication activities*

3.195 In 1993 the CSIRO Division of Plant Industry coordinated the production of 'Will Pigs Fly?', an exhibition that toured eastern Australia for two years explaining the potential uses of gene technology in Australia. An associated teachers education kit was also produced and distributed to schools. Other activities include:

- organisation of the Australian Academy of Science's Science and Industry Forum on Gene Technology at the Maritime Museum, Sydney [Science and Industry Forum web site: http://science.org.au/industry/industry.htm];
- organisation of the inaugural *Discovery* Lecture 'Frontiers of Plant Biology' [website: http://www.pi.csiro.au/Events/Events.htm];
- hosting gene technology briefing sessions;
- preparation of the paper *Future Opportunities for Biotechnology in Australia: Field Crops, Horticulture and Forestry* (commissioned by BA);
- coordination of a series of seven *Cross Country* stories on gene technology covering major CSIRO sectors, which form the basis of CSIRO's *Australia Advances* series 7 [website: http://www.csiro.au/promos/ozadvances/];

- provision of speakers at major forums/events including Australian Science Communicators 'Science in the Pub', the First Australian Consensus Conference on Gene Technology in the Food Chain, the National Farmers Federation Annual Horticulture Conference, University of the Third Age, Food Congress 2000, Seed Industry Association of Australia; and
- coordination of the CSIRO *Discovery Centre* Gene Technology Exhibit.

*The Green Machine Science Education Centre*

3.196 The Green Machine opened in mid 1993 and is part of a national network of CSIRO Science Education Centres. It is currently operated as a joint venture between the ACT Department of Education and Community Services, the Australian National University and CSIRO Education, with support from CSIRO Plant Industry and the Catholic Education Office. Its flagship program is *Gene Technology in Australia* – a workshop presented during Science Festival Week which enables school students and adults to extract DNA from peas and ask questions about the technology [website: http://www.csiro.au/greenmachine/main.html].

3.197 Another program run under the auspices of the Green Machine is the *Industry Link* program, a joint initiative of CSIRO Education and CSIRO Plant Industry. Laboratory and lecture sessions aim to give industry groups and the general public an understanding of fundamental concepts in science. It currently has one course, the Industry Link Plant Gene Technology Workshop, which focuses on explaining plant gene technology in simple terms.

3.198 The Committee is cautious about suggestions that the CSIRO should be the primary Australian disseminator of public information on gene technology,[178] noting that Biotechnology Australia has utilised CSIRO's expertise as part of its public awareness program.

3.199 The Committee is concerned that CSIRO's objectivity may have been compromised by its increasing reliance on funding from industry to support its research, and perceived vested interest in, and enthusiasm for, biotechnology. It concurs with the view that there must be substantial consumer and medical input, as well as the inclusion of a range of other views, regardless of who ultimately issues the material.[179]

3.200 Ms Lisa McDermott observed:

> Many people don't get a chance to read newspapers or read notices of submissions but if the information is brought to people's attention, they will get involved…All opportunities for public input…on GE as well as other

178 See for example, *Committee Hansard*, 25.08.00, p.410 (Australian Food and Grocery Council).

179 *Committee Hansard*, 24.08.00, p.280 (Australian Lactation Consultants Association). See also, *Committee Hansard*, 25.08.00, p.436 (Professor A Gibbs) who argues for a 'plurality of sources of information'.

> matters that effect consumers should be made by way of an announcement on ABC Radio, Triple J (for younger audiences) and ABC television during prime time. It would only take a few minutes of broadcasters' time and it is important community information that I'm sure everyone would wish to know.[180]

3.201 The Committee also notes comments made by virologist, Professor Adrian Gibbs, who considered that universities would be better placed to provide information on gene technology:

> That is their role. I think that is why the public pays taxes for universities to be established. They rely upon universities to try and tell them exactly what the truth is, even if it hears a thousand voices all telling different versions of the truth. CSIRO is very much a corporate body. It is a single body. It has a long history of looking after itself. I believe that, therefore, it is not the only appropriate body and funding should be supplied to other bodies. I believe, in fact, there should be a plurality of sources of information, and that will keep everybody honest.[181]

3.202 The Committee is aware that various organisations[182] provide information on different aspects of gene technology, but considers it vital to establish a 'one-stop' shop for independent, objective and factual information on what is an increasingly controversial issue.

3.203 The Committee considers that measures in the Bill will improve consumer confidence in the regulation of GMOs, but suggests that information on the pros and cons of gene technology must be disseminated to the public by a body that is, and is seen to be, independent from the commercial interests associated with the biotechnology industry.

3.204 In this regard, both CSIRO, although widely and highly respected as a research and education organisation, and the newly established Biotechnology Australia, should be provided with additional support to ensure that the widest possible views are incorporated into publications and other information made available to the public on gene technology.

3.205 The Committee also supports the use of other forms of communication, including television, radio and the Internet, to ensure the widest possible exposure to

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180 Submission No.20, p.4 (Ms L McDermott).

181 *Committee Hansard*, 25.08.00, p.436 (Professor A Gibbs).

182 See for example Agrifood Awareness Australia [http://www.afaa.com.au/], an industry initiative with the following members: the Australian Biotechnology Association, Avcare, the Grains Research and Development Corporation, the National Agricultural Commodities Marketing Association, the National Farmers' Federation and the Seed Industry Association of Australia; See also the Food Science Bureau [http://www.foodsciencebureau.com.au/], an initiative of the Australian Food and Grocery Council. See http://genetech.csiro.au/sites.htm for a listing of Australian and overseas gene technology sites and http://www.icgeb.trieste.it/~bsafesrv/ for biosafety webpages].

arguments both in favour and against the developing technology. The importance of these arguments being presented in an understandable format was also emphasised in evidence:

> I also think those up-to-date scientists… must be prepared to communicate [information] in the language that ordinary people can understand. If they do not, they will never win the trust of the Australian people.[183]

3.206 The Committee agrees with the view expressed by the Tasmanian Government that 'it is essential that the GTR continue to monitor consumer and public confidence in the Office of the GTR and that the Government respond to any emerging concerns with regard to the regulation'.[184]

**Recommendation**

**The Committee RECOMMENDS that an independent organisation conduct a national public education campaign to provide information on the benefits and risks of gene technology, drawing on, but not limited to, the expertise of scientists, primary producers, academics and consumer organisations.**

3.207 While the Bill covers the regulation of all GMOs, by far the greatest concern expressed in evidence was in relation to the regulation of GMOs that were or may become part of the food chain. An AC Nielson Futures study conducted in April 2000 found that 68 per cent of respondents were not happy about eating GM food.[185]

3.208 The Institute of Public Affairs argued, however:

> With regard to the protection of people's health and safety, the new products have undergone greater testing prior to release than any previous food technology. Indeed, although all plant and animal food we now consume has been the creation of human induced cross breeding, no previous food has ever been subject to the oversight required of GM foods.[186]

3.209 The NSW Farmers' Association also pointed to recent safety measures announced by ANZFA:

> …we believe that the measures recently announced by ANZFA…and used by it to assess five genetically modified products are adequate to address consumers' food safety concerns. ANZFA measures carefully assess whether genetic modification gives rise to products containing residual DNA and whether that residual DNA or any other alteration in the

183 *Committee Hansard*, 24.08.00, p.280 (NGAA).

184 Submission No.89, p.4 (Tasmanian Government).

185 Submission No.107, p.20 (Food Industry Council of Tasmania).

186 Submission No.78, p.1 (Institute of Public Affairs Ltd).

> composition of the GM product give rise to additional allergenic or toxicity problems.[187]

3.210 Surveys conducted by Consumer Science Program between 1994 and 1999 show little change in community attitudes over the period with a slight lessening of support for genetically engineered foods based primarily on:

- concerns with the involvement of large corporations;
- increased availability of information on the subject;
- fear of science and technology taking over; and
- concern with environmental and health effects.[188]

3.211 Australian consumer concerns about GM food is mirrored overseas, particularly in the United Kingdom, Western European countries and Japan, with similar trends emerging in New Zealand, South Korea and the United States.[189]

3.212 The National Farmers' Federation observed public confidence, may in part, be lacking because of less than obvious benefits to the consumer:

> One of the barriers to consumer acceptance at this stage appears to be the fact that there is currently little discernible benefit to consumers in the products on shelves. Many of the biotechnological characteristics developed so far benefit agricultural inputs, for example they may be drought resistant or salt tolerant. However, it is difficult for those benefits to be extrapolated to the finished product, so that consumers can see [and taste] the benefits as well.[190]

3.213 However, Dr Tribe of the Australian Biotechnology Association argued that acceptance of GM food will follow the same path as genetically modified pharmaceuticals. In relation to the acceptance of GM pharmaceuticals, he stated:

> Perhaps it is related to the fact that, once tangible benefits from gene technology became obvious around 1982, the anti-GMO people gave up claiming that medicine was dangerous in this area because the record showed that tangible benefits would occur. And I hazard a guess that, since agriculture is lagging behind by about 10 years in the implementation of this technology, once clear-cut examples of obvious benefits to the consumer– such as golden rice–reach the market place, you might see quite different attitudes. The historical snap shot we are looking at at the present time may

187 Submission No.76, p.3 (NSW Farmers' Association).

188 Submission No.107, pp.20-1 (Food Industry Council of Tasmania).

189 Submission No.107, p.12 (Food Industry Council of Tasmania). Concerns were also expressed about US GM wheat in Japan, the Philippines, Vietnam, Malaysia, Singapore, Thailand, Bangladesh and Egypt, reported in *Wheat industry promises to segregate biotech wheat*, AAP, 30 June 2000.

190 Submission No.88, Attachment 3, p.17 (National Farmers' Federation).

> change when demonstration of what is going to happen takes place. So that is one factor.[191]

3.214 Some applications of genetic engineering do appear to have greater public acceptance including in the areas of pharmaceuticals, pollution control, waste management and cut flowers.[192] Public confidence in the regulation of pharmaceuticals is also perceived by the public to be more stringent and the benefits more tangible than the current regulatory arrangements for GM food. An explanation of this view was expressed by the Organic Federation of Australia:

> …we see pharmaceutical [gene technology] as not involving the release of live organisms, so the risk is much less; it provides medicines which are taken in small quantities for short periods of time when people are in a compromised position. We believe that the use of gene technology in those circumstances is warranted. In terms of food, it does involve the release of live organisms…[193]

3.215 While public acceptance is higher where either the exposure of an individual to a GMO has been for medical treatment or where genetically modified plants are not destined for the food chain, particular concerns are felt in relation to the use of bacteria and viruses in gene technology, and transgenic organisms, that is, cross species transfer of genes, for example transferring fish genes into tomatoes.[194]

3.216 Mr Kinnear of the Organic Federation of Australia stated:

> When we insert a piece of DNA somewhere, there are other consequences in doing that. We may disrupt other genes on either side, we may turn on or off, or…you actually cause other genes that are already there to express proteins or cause proteins to build up in much higher concentrations than have ever existed before in that tomato plant, for example. So that tomato which we are used to is changing in its protein nutrient status…we are dealing with unknown quantities here. Perhaps 999 out of 1,000 of these products might be fine, and history may tell us that they are fine, but we have to really carefully consider our duty of care. How many generations should we think down the track? Are we here for another 100 years, or are we here for 1,000 years, and what are the implications of our activities?[195]

3.217 Mr Burgess from the SA Farmers Federation indicated that while the organisation did not, as yet, have a policy position on cross species genetic modification, for example, the transferring of a salmon gene into a strawberry:

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191 *Committee Hansard*, 24.08.00, p.259 (ABA).

192 See for example results of 1998 Consumer Science Program survey discussed in the National Science & Industry Forum Report, April 1999, p.15. See also, *Committee Hansard*, 24.08.00, pp.258-9 (ABA).

193 *Committee Hansard*, 23.08.00, p.138 (Organic Federation of Australia). See also *Committee Hansard*, 23.08.00, p.233 (Tasmanian Government); C*ommittee Hansard*, 24.08.00, p.276 (NGAA).

194 See for example, *Committee Hansard*, 23.08.00, p.174 (GE-Free Tasmania); p.193 (Serve-Ag).

195 *Committee Hansard*, 23.08.00, p.158 (OFA).

> …if the scientific evidence supports it, given that there are, say, three million genes in a single strand of DNA, to introduce a minor amount of 15 to 20 genes from another species is not going to change the whole organism so dramatically as to be a major problem. But there are ethical issues…that will need to be handled.[196]

3.218 The National Farmers' Federation commented that 'more needs to be done to ensure consumers are exercising informed choice and are not being led by media scare campaigns, for example "Frankenstein foods"'.[197]

3.219 The Committee considers that a combination of tighter regulation provided by the Gene Technology Bill and a national education campaign to inform the community about the benefits, risks and measures designed to control the development and adoption of new gene technologies, will improve consumer confidence.

3.220 The Committee is also conscious that any proposed changes to the Bill made at this stage would require agreement from the States and Territories to ensure a truly national scheme, and that anything less may adversely impact on consumer confidence in the regulatory process.[198]

3.221 The Committee considers that the Gene Technology Bill provides an adequate regulatory regime to ensure the protection of the health and safety of people and the environment, and includes public reporting provisions that should help to enhance consumer confidence in the regulation of the development and adoption of new and existing gene technologies. However, the Committee considers that some of the proposed regulatory arrangements and reporting provisions require strengthening, and has made recommendations to improve the Bill in this and subsequent chapters.

**Review of gene technology legislation**

3.222 While the Committee supports the Bill, it is likely that in establishing the new national regulatory scheme, the Regulator will experience problems in implementing certain aspects of, and ensuring compliance with, the new regulatory system. The IOGTR advised the Committee that it is proposed that the Ministerial Council undertake a comprehensive review of the legislative scheme no later than 5 years after the commencement of the scheme.[199] However, the Committee considers that given the fundamental importance of the issues involved, the timeframe, in which the proposed review is to take place, is too long.

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196 *Committee Hansard*, 22/08/00, p.57 (SA Farmers Federation).

197 Submission No.88, Attachment 3, p.17 (National Farmers' Federation).

198 See for example, the comments in Submission No.115, p.1 (Victorian Government). See also Submission No.110, p.2 (South Australian Government) which also refers to the opportunity for future review of the legislation.

199 Submission No.77, p.132 (IOGTR).

**Recommendation**

**The Committee RECOMMENDS that the operation of the Act should be independently reviewed after three years to ensure that its objects are being met.**